Our decision for FOI 2016-40. Section 36 (2) (b) and (c) was challenged by the requester. Following an internal review the requester complained to the Information Commissioner.

The Information Commissioner's Office reviewed the request and produced their determination (Reference: FS50689175).

In response to their determination we have decided in the interest of transparency that we will publish the ICO determination as well as the minutes of the Stakeholder Working and Steering Groups.

The ICO determination and as well as the minutes have been redacted by virtue of Section 40 of the Freedom of Information Act – Personal Information. This means all personal information/ identifiers related to third parties have been removed.

Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 7 November 2017

Public Authority: General Optical Council
Address: 10 Old Bailey
London
EC4M 7NG

Complainant:
Address: [redacted]

Decision (including any steps ordered)

1. The complainant has requested communication exchanges between the General Optical Council (GOC) and its Stakeholder Group about the formulation of a particular code. GOC's position is that the requested information is exempt from release under section 36(2)(b) and (c) of the FOIA as it considers that disclosing it would inhibit the free and frank provision of advice and views, or would otherwise prejudice the effective conduct of public affairs.

2. The Commissioner's decision is that:

   - Sections 36(2)(b)(i) and (ii) are engaged but that the public interest favours disclosing the requested information.

   - Section 36(2)(c) is not engaged.

3. The Commissioner requires the public authority to take the following step to ensure compliance with the legislation:

   - Release the requested information to the complainant, with personal data redacted in line with section 40(2) of the FOIA, as appropriate.

4. The public authority must take these steps within 35 calendar days of the date of this decision notice. Failure to comply may result in the Commissioner making written certification of this fact to the High Court

pursuant to section 54 of the Act and may be dealt with as a contempt of court.

Request and response

5. On 27 October 2016, the complainant wrote to GOC and requested information in the following terms:

"I am requesting copies of the exchanges of communication between the GOC and its Stakeholder Group relating to the formulation of the Voluntary Code. The time-period is the time-period over which this communication took place."

6. In correspondence dated 16 November 2016, GOC indicated that the requested information was exempt from disclosure under section 36(2)(b) and (c) of the FOIA and that it was seeking the opinion of a qualified person. On 15 December 2016, GOC provided a response to the request confirming its reliance on section 36(2)(b) and (c) and that it considered that the public interest favoured maintaining the exemptions.

7. GOC provided an internal review on 21 February 2017. It upheld its position and addressed the complainant's concerns about a particular policy.

Scope of the case

8. The complainant contacted the Commissioner on 4 July 2017 to complain about the way his request for information had been handled.

9. The Commissioner's investigation has focussed on GOC's application of section 36(2)(b) and (c) to the complainant's request and the balance of the public interest.

Reasons for decision

10. GOC has provided the Commissioner with a background to the complaint, which it considers has a bearing on the public interest arguments that the complainant has put forward.

11. GOC has explained that, as the regulator for UK optometrists and dispensing opticians, it has a clearly defined public protection remit. For

it to be effective it needs the trust and engagement of both the public and its stakeholders.

12. GOC says that the complainant has been in communication with it for a prolonged period regarding the issue of contact lens substitution, at a senior level. The Commissioner understands that 'contact lens (or brand) substitution' refers to issues associated with the practice of buying contact lenses online, particularly in cases where a customer's current contact lens is substituted with a contact lens that is different from a customer's specification. GOC says it has tried to actively engage with the complainant regarding the issue of contact lens substitution and, in March 2016, met him to discuss the matter at length. To date, the complainant remains dissatisfied with the responses GOC has provided.

13. The issue of brand substitution was discussed at length by a Stakeholder Working Group and Steering Group, when drafting a proposed Voluntary Code for online contact lens suppliers. After discussion within the group, the proposed Voluntary Code was opened up to public consultation.

14. GOC has told the Commissioner that the complainant told it that he was unable to engage with the Group during discussions about substitution. GOC has noted that the consultation was open to all without restriction and that the complainant did provide a lengthy submission to the consultation in October 2015. The outcome of the consultation was subsequently published on GOC's website in order to be transparent and forthcoming about the debate and concerns raised.

15. GOC considers it is pertinent that, although the complainant considers that he was not involved in the Working Group, he did attempt to influence the decision of the Group by engaging a lawyer to write an open letter to the Group members stating all legal options would remain open if the Group's decision was one that was at odds with the complainant's opinion, and not in the interest of a business that he owns.

16. When the consultation outcome was published, GOC says that the complainant complained that too much information had been published and the responses to the consultation (which were published verbatim) would damage his business. GOC says that the complainant has repeatedly asked for a public apology for the publication of a response to the consultation that he did not agree with.

17. Following the consultation, a decision was taken that there was no evidence to suggest any risk with brand substitution and, as such, the requester's business interests were not damaged or impeded. This information; that is, that there was no evidence to support risks

associated with brand substitution, was communicated online to the public via GOC's website. The Commissioner understands that the decision was subsequently taken to withdraw the proposed Voluntary Code.

Section 36 – prejudice to the effective conduct of public affairs

18. GOC's position is that the information it holds that falls within the scope of the complainant's request, to which it has applied section 36, is the minutes from a series of Stakeholder Working Group meetings that took place during 2015.

19. Section 36(2)(b) says that information is exempt information if disclosure would, or would be likely to, inhibit (i) the free and frank provision of advice or (ii) the free and frank exchange of views for the purposes of deliberation. Section 36(2)(c) says that information is exempt information if disclosure would otherwise prejudice, or would be likely otherwise to prejudice, the effective conduct of public affairs.

20. Section 36 differs from all other prejudice exemptions in that the judgement about prejudice must be made by the legally authorised, qualified person for that public authority. The qualified person's opinion must also be a "reasonable" opinion, and the Commissioner may decide that the section 36 exemption has not been properly applied if she finds that the opinion given is not reasonable.

21. Other than for information held by Parliament, section 36 is a qualified exemption. This means that even if the qualified person considers that disclosure would cause harm, or would be likely to cause harm, the public interest must still be considered.

22. To determine, first, whether GOC correctly applied the exemption, the Commissioner is required to consider the qualified person's opinion as well as the reasoning that informed the opinion. Therefore in order to establish that the exemption has been applied correctly the Commissioner must:

    - ascertain who was the qualified person or persons
    - establish that an opinion was given by the qualified person
    - ascertain when the opinion was given; and
    - consider whether the opinion was reasonable.

23. From the information GOC has provided to her, the Commissioner notes that the qualified person was GOC's then Chief Executive/Registrar, Samantha Peters.

24. Ms Peters' opinion was sought on 12 December 2016 and she was provided with GOC's correspondence with the complainant about his FOI request and wider concerns, Stakeholder Working Group minutes and email correspondence from members of the Stakeholder Working Group and Steering Group. GOC has told the Commissioner that Ms Peters also discussed the matter with its Director of Strategy, Compliance Manager and Compliance Officer. GOC has provided the Commissioner with copies of the written material and a copy of Ms Peters' opinion, which the Commissioner has reviewed as part of her considerations.

25. Ms Peters' opinion was that sections 36(2)(b)(i), 36(2)(b)(ii) and 36(2)(c) were engaged.

26. The Commissioner is satisfied that the opinion was that of the appropriate qualified person for GOC. She has gone on to consider whether that opinion is reasonable. It is important to note that this is not determined by whether the Commissioner agrees with the opinion provided but whether the opinion is in accordance with reason. In other words, is it an opinion that a reasonable person could hold. This only requires that it is a reasonable opinion, and not necessarily the most reasonable opinion. The test of reasonableness is not meant to be a high hurdle and if the Commissioner accepts that the opinion is one that a reasonable person could hold, she must find that the exemption is engaged.

27. With regard to section 36(2)(b)(i), Ms Peters' view was that prejudice would be likely to occur if the requested information was disclosed as stakeholders would be less likely to engage with GOC on this and other issues. With regard to sections 36(2)(b)(ii) and 36(2)(c), Ms Peters' view was that prejudice would occur because, to enable the continued success of GOC and the optical centre as a whole, discussions must take place in a secure environment to facilitate free and frank discussion. She considered that releasing the requested information would make stakeholders less likely to engage.

28. As a prejudice-based exemption, section 36(2) necessitates that a decision is made about whether there 'would' be a harmful effect as a result of disclosure or whether it 'would be likely' that the harmful effect would occur; 'would' imposing a stronger evidential burden that the lower threshold of 'would be likely'.

29. With regard to section 36(2)(b), the Commissioner considers that the exemption concerns processes that may be inhibited in the future, rather than harm arising from the content or subject matter of the requested information itself. The key issue in this case is whether disclosure could inhibit the process of providing free and frank advice for the purposes of deliberation.

30. Section 36(2)(c), on the other hand, refers to the prejudice that would be likely otherwise to apply. The Commissioner considers that if section 36(2)(c) is used in conjunction with any other exemption, as in this case, the prejudice envisaged must be different to that covered by the other exemption.

31. With regard to the above point, the Commissioner notes that the qualified person's position is that the effective conduct of public affairs would be prejudiced because the free and frank provision of advice would be inhibited. No separate and different prejudice has been identified. Consequently, the Commissioner does not consider section 36(2)(c) to be engaged as the arguments relied upon by Ms Peters appear to relate only to section 36(2)(b)(i) and 36(2)(b)(ii).

32. The Commissioner is satisfied that the qualified person's opinion that sections 36(2)(b)(i) and 36(2)(b)(ii) are engaged is a reasonable opinion to hold. The opinion given addresses the relevant issues and expresses a reasoned view on the likely impact of disclosure. She has therefore concluded that the withheld information does engage these particular exemptions in this case.

33. The Commissioner has noted that, in its wider submission to the Commissioner, GOC has told her that the Stakeholder Working and Steering Groups comprised of external members from the optical professions as well as a patient representative. At the time of their formation, members of the Groups were informed that discussions within the Group would remain confidential. Members of the Group were required to sign an undertaking that GOC information presented to the Group during the meetings must not be shared outside of the Group. Because of this, GOC considers that it would not be unreasonable for members to believe that this would also apply to information they shared within the Group during these discussions.

Public interest test

34. Section 36(2)(b)(i) and section 36(2)(b)(ii) are qualified exemptions so the public interest test set out in section 2(2)(b) of the FOIA must be applied. The requested information, though exempt, can only be withheld if the public interest in maintaining the exemption outweighs the public interest in disclosure.

35. With regard to section 36(2)(b)(i), the Commissioner notes that it was the qualified person's opinion that disclosure of the withheld information '*would be likely*' to have the effects set out in sections 36(2)(b)(i), as opposed to that it 'would' have those effects. In her view this means that there is a real and significant chance of the prejudice occurring, even though the probability may be less than fifty per cent. The

Commissioner has taken this into account in assessing the public interest arguments in favour of maintaining the exemption.

36. With regard to section 36(2)(b)(ii), the Commissioner notes that it was the qualified person's opinion that disclosure of the withheld information '*would*' have the effects set out in sections 36(2)(b)(ii), as opposed to that it 'would be likely to' have those effects. 'Would prejudice' means that it is more likely than not (ie a more than 50% chance) that prejudice would occur.

37. Following the Information Tribunal's decision in (EA/2006/0011 & EA/2006/0013), it is the Commissioner's opinion that while due weight should be given to the reasonable opinion of the qualified person when assessing the public interest, the Commissioner can and should consider the severity, extent and frequency of the likely inhibition on the free and frank provision of advice, the free and frank exchanges of views for the purposes of deliberation and the likely prejudice to the effective conduct of public affairs.

38. GOC considered the following factors for disclosure:

- Disclosing the requested information may increase the quality of the advice it receives for its stakeholders.

- The content of its deliberation may be enhanced if there was the expectation that related information would be made public.

39. The Commissioner considers there is also a general argument for disclosure on the grounds that it demonstrates transparency and accountability on behalf of the public authority concerned. She has noted, from the information GOC has provided to her, that one or two of the members of the Stakeholder Group appear to consider this argument is valid in this case.

40. GOC considered the following factors against disclosure:

- Discussions about substitution have been transparent, as evidenced by the public consultation, publication of the verbatim responses and outcome of the consultation.

- It is important that free and frank discussions can be held in private in order for GOC to make appropriate decisions in the interests of protecting the public – which remains its priority. GOC considers that releasing the withheld information would significantly damage stakeholder trust in GOC and would make stakeholders less likely to engage with it in its public protection function. GOC argues that this would therefore prejudice the effective conduct of public affairs.

- With regard to the consultation, GOC notes that the final decision was that the Voluntary Code was discontinued and that decision has been published.

- Releasing the information risks confusing the public on the issue of substitution.

41. In a submission to the Commissioner dated 20 September 2017, the complainant presented the following arguments for disclosure:

    - The need for a Voluntary Code was predicated on the belief that 'brand substitution' of soft spherical contact lenses, whilst not illegal, carried public health risks unless the transaction was approved in advance by an optician. The complainant considers there has never been any evidence to justify this.

    - A consequence of the Voluntary Code, had it been implemented, would have been to put out of business a particular company that makes unbranded daily disposable contact lenses.

    - The public should know whether the Stakeholder Group (whose members include the Association of Contact Lens Manufactures and particular retailers) advised GOC that there is no risk to the public by brand substitution and, if the Group did advise GOC to this effect, why GOC continued to proceed with the Voluntary Code.

Balance of the public interest

42. As above, the position of GOC's qualified person is that, with regard to section36(2)(b)(i), disclosure would be likely to inhibit the free and frank provision of advice and that, with regard to section 36(2)(b)(ii), disclosure would inhibit the free and frank exchange of views for the purposes of deliberation. The Commissioner is satisfied that these are reasonable opinions to hold and that these exemptions are engaged.

43. The Commissioner has gone on to consider the severity, extent and frequency of that inhibition in forming her own assessment of whether the public interest test dictates disclosure.

44. GOC's public interest arguments against disclosing the requested information centre on disclosure diminishing stakeholders' ability to discuss matters freely and in private – the so called 'chilling effect' – and that disclosure would diminish stakeholders' trust in GOC and make them less likely to engage with it.

45. The Commissioner has noted that the Stakeholder Group meetings, to which the withheld information is associated, had taken place during the

previous year – 2015 - at the time of the request in October 2016. The Group had been convened to discuss the merits of a Voluntary Code concerned with retailing particular contact lenses online. A Draft Voluntary Code was prepared and published but the decision was subsequently taken to withdraw the proposed Code.

46. As discussed in her published guidance on section 36[1], chilling effect arguments operate at various levels. If the issue in question is still live, arguments about a chilling effect on those ongoing discussions are likely to be most convincing. Arguments about the effect on closely related live issues may also be relevant. However, once the decision in question is finalised, chilling effect arguments become more and more speculative as time passes. It will be more difficult to make reasonable arguments about a generalised chilling effect on all future discussions.

47. Whether it is reasonable to think that a chilling effect would occur will depend on the circumstances of each case, including the timing of the request, whether the issue is still live, and the actual content and sensitivity of the information in question.

48. The Commissioner does not find GOC's public interest arguments for withholding the information compelling. It seems to her that, at the time of the request, the business of the Voluntary Code was no longer current. Releasing the requested information during 2015, or while deliberations about whether or not to confirm the Voluntary Code were ongoing, *may* have inhibited those involved in the discussions. However, the deliberations in this case were concluded at the time of the request and, in the Commissioner's view, the content of the information in question is not, in the scheme of things, especially sensitive. She is therefore not persuaded that the specific Stakeholder Group in question could now be inhibited if the information was to be released.

49. Nor has the Commissioner been persuaded, by the information that GOC has provided to her, that free and frank exchange of views and provision of advice would, or would be likely to be inhibited in the future if the requested information was to be released. The qualified person has stated that inhibition would, or would be likely to, occur and that disclosure would make stakeholders less likely to engage with it. But

[1] https://ico.org.uk/media/for-organisations/documents/1175/section_36_prejudice_to_effective_conduct_of_public_affairs.pdf

the qualified person has not provided any more information or evidence to support this opinion.

50. The Commissioner has noted, in GOC's submission, its description of the history between it and its Working Group and the complainant. However, she does not consider that this is robust evidence that stakeholders would be less likely to engage with it in the future if the requested information was to be released.

51. The Commissioner has, however, also noted that the public interest arguments for disclosure that the complainant has put forward are limited to the interest he has in its release, and not any wider public interest there may be in the information. In the Commissioner's view, the requested information has little wider public interest, particularly since the Voluntary Code was withdrawn and no individual or business was therefore affected by it.

52. That said, because she finds there is no compelling public interest reason for withholding the information, she finds that the general public interest in public authorities being transparent and accountable is of sufficient weight to tip the balance in favour of disclosure on this occasion.

Right of appeal

53. Either party has the right to appeal against this decision notice to the First-tier Tribunal (Information Rights). Information about the appeals process may be obtained from:

    First-tier Tribunal (Information Rights)
    GRC & GRP Tribunals
    PO Box 9300
    LEICESTER
    LE1 8DJ

    Tel: 0300 1234504
    Fax: 0870 739 5836
    Email: GRC@hmcts.gsi.gov.uk
    Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

54. If you wish to appeal against a decision notice, you can obtain information on how to appeal along with the relevant forms from the Information Tribunal website.

55. Any Notice of Appeal should be served on the Tribunal within 28 (calendar) days of the date on which this decision notice is sent.

Signed .....

Pamela Clements
Group Manager
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Stakeholder steering group on contact lens supply

Wednesday 4 February, 2015

General Optical Council (GOC) offices

GOC attendees: [redacted], [redacted]

Attendees: [redacted]

Apologies: [redacted]

Minutes taken by: [redacted]

1. Welcome and attendees

[redacted] welcomed the meeting attendees and each member of the group introduced themselves.

2. Regulatory approach

[redacted] explained that the GOC had decided to review its illegal practice strategy last year and had come to the conclusion that we needed to re-think our approach. It is no longer appropriate to just react to complaints. We commissioned some research from Europe Economics into the risks associated with different types of illegal practice. The GOC's new strategy covers all types of illegal practice but we are particularly concerned about online contact lens supply and zero-powered (also known as cosmetic) contact lenses. There are limitations with a traditional enforcement approach and so we have agreed to take forward a multi-pronged strategy including:

- 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 (for example, working with the General Pharmaceutical Council (GPhC) where pharmacies are selling zero-powered contact lenses illegally);
- 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, including to evaluate the impact of the strategy.

Regulation has traditionally focused on supply but that is not effective as supply of contact lenses is often from outside the UK where we have no jurisdiction. In addition, zero-powered contact lenses are supplied by numerous small outlets up and down the country and we cannot afford to take action against them all due to limited resources.

We have therefore decided to focus on the demand side of contact lenses, by making consumers aware of where they can safely buy contact lenses and making it easier for them to choose a supplier that follows good practice by promoting the voluntary code.

A voluntary code is effectively a form of self-regulation. There are models of self-regulation that are a substitute for formal regulation, for example in advertising, and models that use self-regulation to complement formal regulation. We are aiming to do the latter in that the code of practice will be going beyond the legal requirements to include best practice as currently recognised. The Office of Fair Trading set up a consumer codes approval scheme to provide guidance for those interested in setting up codes of practice, which is now run by the Trading Standards Institute. The British Healthcare Trades Association has a voluntary code of practice for its 500 member companies (http://www.bhta.net/), which goes beyond legal obligations and provides a way for its members to highlight their commitment to following good practice.

Examples of where the code of practice might go beyond legal requirements is in the area of substitution, which is not technically illegal but where our research suggests that in certain circumstances there is a risk of public harm and good practice might involve restricting the circumstances in which substitution take place. We also want to ensure that people are given appropriate aftercare advice.

3. Objectives for the project

[redacted] shared his view that we are here because of the challenges with the existing legislation, which came into force before a lot of the technology that exists today. One particular example is the requirement to verify a contact lens specification with the provider, although there is no duty on the provider to give that information and the legislation does not strictly require a supplier to supply exactly to the specification.

There are three illegal practices that relate to contact lens supply and around 95 per cent of interest in the concerns around illegal practice seems to be in online supply. It is interesting to note that the vast majority of the complaints the GOC receives around illegal practice are received from registrants, not members of the public.

The role of the stakeholder steering group on contact lens supply is to empower the stakeholder working group on the voluntary code of practice. We will need to agree the key elements or anchor points that a code of practice should have and task the working group to produce this. A second piece of work will be around advice on safe contact lens wear for consumers.

It was confirmed that everyone had read the terms of reference and the pre-reading distributed before the meeting. The terms of reference for the group were agreed as drafted.

4. Evidence

[redacted] gave a presentation. [redacted] explained that the main challenge when considering illegal lens supply is its impact on the risk of contact lens infection. The incidence of infection is extremely small and there have only been a few studies which have reported on the incidence in this area in the last 25 years. Also, such studies are complex to undertake. Most estimates have the likelihood of infection at around two per 10,000 wearers per year for daily wear and perhaps four to six times this for

extended wear. The likelihood of losing vision is rarer (about ten per cent of the numbers above), and infections are usually in one eye only. It is therefore very difficult to identify the risk factors associated with corneal infection (particularly if you want to look at the way that the lenses are supplied). The only way we could research the risk factors in more detail would be to monitor hospital A&E departments for a significant period of time and ask detailed questions about use and supply. You would then have to ask the same questions of those who wear contact lenses but do not have a corneal infection and compare the two datasets. This is difficult and expensive.

A small project on corneal infection was carried out ten years ago in Manchester. The largest study of this kind was carried out in Australia by Stapleton et al[1], which looked at corneal infection due to contact lens use in hospitals across the whole country for one year. Given the paucity of data, we need to learn what we can from these studies. Stapleton et al found that those who obtained their lenses via mail order or internet supply were 4.8 times more likely to get a corneal infection than those had not done so. We can only speculate about why this might be the case – perhaps it is that they are more likely to be risk-takers and not follow good hygiene practice in relation to lenses. But this is a genuine result which is very unlikely to be due to chance and as with any meaningful outcome from these difficult studies, we should carefully consider its importance.

[redacted] said that a recent study had suggested that behaviour (in relation to good hygiene practice for contact lenses) does improve if people are re-trained. [redacted] suggested that we might wish to focus on encouraging handwashing (reusable and disposable lenses), rubbing and washing (reusable) lenses and case cleaning (reusable lenses).

[redacted] suggested that there are other campaigns that we should be aware of being carried out by the Medicines and Healthcare products Regulatory Agency (MHRA), Moorfields Eye Hospital (*Healthy Habits, Healthy Eyes* poster) and the British Contact Lens Association (BCLA) campaign.

5. Insights from pharmacy

[redacted] outlined the issues that had occurred in pharmacy and online medical supplies in the last 20 years, including compliance with the EU directive on falsified medicines. The concerns first arose as a commercial issue – online pharmacy services had started up in the late 1990s selling health and wellbeing products not available on the NHS and/or those that might cause embarrassment when discussing with a GP (for example, male pattern baldness, obesity medicines, erectile dysfunction medication). At that time there were one or two prosecutions by the Royal Pharmaceutical Society (RPS) (then the regulators for pharmacists in the UK). There had also been some problems with counterfeit medicines. Websites included non-UK based companies varying from the Channel Islands to further abroad.

The 'registered pharmacy' project was set up so that legitimate online pharmacies could register with the RPS (now the GPhC) and use a logo containing their registration number on their website, which had a direct link to the register when clicked on. The application cost £50 and is now policed by the GPhC inspection team. There was a communications campaign when the logo was launched 12-15 years ago, to both the profession and the public, but since then there has not been much else.

[1] Stapleton F, et al. The incidence of contact lens-related microbial keratitis in Australia *Ophthalmology*, 2008; 115(10): p 1655-1662.

The GPhC do intend to do more and this is a timely issue for them as they recently consulted on a new set of standards for internet selling, which they will be analysing the results of now.

[redacted] said that it would be helpful to prove that having the registered pharmacy logo made a difference to people's shopping habits. [redacted] was not aware of any data available to track this. He wondered if the trade sectors should be doing something more to promote use of registered pharmacies. He was not sure if it had made any difference to UK suppliers as they would have already been set up as pharmacies anyway. He mentioned a Pfizer advertisement campaign several years ago that was warning about buying medicines from the internet.

[redacted] advised that the EU falsified medicines directive would make use of a logo for online pharmacies obligatory to provide public assurance. The EU directive is in the process of being implemented/transposed. The registerable body for the logo would be the MHRA so we may wish to contact them. It will be for the GPhC to decide whether to continue the current logo. It is monitored quite well but it is not clear whether it means anything to consumers at the current time.

[redacted] noted that the regulators (MHRA and EU counterparts) appeared to be working hard to seek out counterfeit products and there were often articles in the press with stories about suppliers who had been shut down. [redacted] also noted that illegal supply of a medicine was a criminal offence.

[redacted] left the meeting at this point. [redacted] was thanked for his presentation which was thought to be very useful.

6. Project plan and timeline

[redacted] advised that the current project timeline was likely to be as follows:

- 4 Feb '15: first meeting of stakeholder steering group
- 4 Feb '15: first meeting of stakeholder working group; initial draft of code of practice
- 4 Mar '15: second meeting of stakeholder working group; finalise draft of code of practice
- 27 Mar'15: second meeting of stakeholder steering group – sign off proposed code of practice and proposals for monitoring the code for presenting to GOC Council meeting on 13 May
- 27 Mar '15: first meeting of stakeholder working group on consumer awareness
- 20 May '15 - 12 Aug '15: consultation on voluntary code of practice; hold consultation event; meet with suppliers; develop consumer awareness messages and draft guidance for consumers
- Sept '15: review outcome of consultation and finalise code of practice and proposals for monitoring the code
- 21-27 Sept '15: begin distributing consumer awareness messages in National Eye Health Week
- 11 Nov '15: Council meeting to approve voluntary code of practice and how the code will be monitored
- 1 Dec '15: Launch voluntary code of practice

7. Voluntary code of practice for online contact lens supply

[redacted] explained the principle of a voluntary code of practice and asked the group what would be the key anchor points that we would like to pass on to the working group to consider. The following points were raised:

- contact lenses being supplied to a valid specification (but without necessarily having to have the original copy or telephoning to check the specification);
- value – it must be clear why online suppliers would want to adopt the code: 'why wouldn't you want to sign up to this?';
- substitution – we need the clinician's message to get through and the high street needs to be enfranchised (so the code needs to reflect the role of practitioners and not just that of online suppliers);
- providing standard information such as clear prices, cancellation details, selling regulations, commitment not to mislead, assurance from consumer that they are 16 or over and not visually impaired; and
- it should come with a logo.

There was suggestion of there being a requirement for a kind of 'data warehouse' to pool data on customer specifications but it was felt that it would be problematic to impose the extra administrative costs on businesses at this stage.

It was also noted that re-educating the profession would be important, so there should be a launch for both registrants and online suppliers.

There was not thought to be a big problem with counterfeit contact lenses although there had been some occurrences of contact lenses being re-packaged incorrectly and mis-sold.

There was discussion around whether the code should be run by the GOC. Some felt it was not appropriate for it to be run by the GOC. There was suggestion that it could be run by a trade association to get everyone on side.

We need to be clear about the obligations on EU providers as covered by EU directives, for example, consumer complaints. It was noted that EUROMCONTACT deal with complaints.

There was a question about whether it was expected that anyone signing up to the code would be a GOC business registrant. It was not clear whether this would be necessary and may well not be possible under existing body corporate legislation.

8. Consumer awareness

[redacted] advised that we also need to start thinking about the consumer awareness side of things and the messages that we might want to give out. The following points were noted:

- collaboration with other bodies so that we are all saying the same message was very important (e.g. optical bodies, manufacturers and multiples);
- less is more – we should consider concentrating on the top three risks;
- slowly build up good messages – different positive reminders could be used over time;

- consumer awareness messages shouldn't just be website-based – could be a leaflet given out by optometrists/dispensing opticians (the old Department of Health leaflet had space for a signature and a tear-off slip for the patient record);
- a leaflet could contain consistent 'top tips' with a basic level of info;
- people need to be aware of the code of practice; and
- suggestion of celebrity endorsement to promote the message.

[redacted] advised that the BCLA had recently met with the MHRA who advised that they expect the BCLA (and other associations) to deliver the solutions to the problems of contact lens supply.

9. Feedback

[redacted] thanked everyone for their contributions and advised that the working group would be meeting that afternoon to start thinking about what the code might look like and how it could be monitored.

10. Review and next steps

[redacted] thanked everyone for their input and time.

11. Date and time of next meeting

[redacted] advised that the next meeting of the stakeholder steering group will be on 27 March 2015 at 11am.

Stakeholder working group on the voluntary code of practice for online contact lens supply

Wednesday 4 February, 2015

GOC offices

GOC attendees: [redacted]

Attendees: [redacted]

Apologies [redacted]

Minutes taken by: [redacted]

1. Welcome and attendees

[redacted] welcomed the meeting attendees and each member of the group introduced themselves.

2. Regulatory approach

[redacted] explained that the GOC had decided to review its illegal practice strategy last year and had come to the conclusion that we needed to re-think our approach. It is no longer appropriate to just react to complaints. We commissioned some research from Europe Economics into the risks associated with different types of illegal practice. The GOC's new strategy covers all types of illegal practice but we are particularly concerned about online contact lens supply and zero-powered (also known as cosmetic) contact lenses. There are limitations with a traditional enforcement approach and so we have agreed to take forward a multi-pronged strategy including:

- 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 (for example, working with the General Pharmaceutical Council (GPhC) where pharmacies are selling zero-powered contact lenses illegally);
- 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, including to evaluate the impact of the strategy.

Regulation has traditionally focused on supply but that is not effective as supply of contact lenses is often from outside the UK where we have no jurisdiction. In addition, zero-powered contact lenses are supplied by numerous small outlets up and down the country and we cannot afford to take action against them all due to limited resources.

We have therefore decided to focus on the demand side of contact lenses, by making consumers aware of where they can safely buy contact lenses and making it easier for them to choose a supplier that follows good practice by promoting the voluntary code.

A voluntary code is effectively a form of self-regulation. There are models of self-regulation that are a substitute for formal regulation, for example in advertising, and models that use self-regulation to complement formal regulation. We are aiming to do the latter in that the code of practice will be going beyond the legal requirements to include best practice as currently recognised. The Office of Fair Trading set up a consumer codes approval scheme to provide guidance for those interested in setting up codes of practice, which is now run by the Trading Standards Institute. The British Healthcare Trades Association has a voluntary code of practice for its 500 member companies (http://www.bhta.net/), which goes beyond legal obligations and provides a way for its members to highlight their commitment to following good practice.

Examples of where the code of practice might go beyond legal requirements is in the area of substitution, which is not technically illegal but where our research suggests that in certain circumstances there is a risk of public harm and good practice might involve restricting the circumstances in which substitution take place. We also want to ensure that people are given appropriate aftercare advice.

3. Objectives for the working group

[redacted] summarised the earlier stakeholder steering group meeting including the interesting presentation from [redacted] on research into infections caused by contact lens wear and the insights from pharmacy shared by [redacted].

The terms of reference were agreed as drafted.

[redacted] outlined the feedback and suggestions for what should be included in a voluntary code of practice.

4. Key principles for the voluntary code of practice

There was discussion around the need for guidance for registrants around completing a specification for contact lens (and on when the fitting should be regarded as having been completed). The group noted that the College of Optometrists provides guidance for registrants on this area, including how to respond to a telephone call requesting verification of a specification. It was also noted that the College guidance suggests that registrants can be helpful but ambiguous so as to assure compliance with data protection legislation.

The discussion around substitution included reference to manufacturers producing publicly available 'fit match statements' in circumstances where one lens could legitimately be substituted for another.

It was felt that it would not be appropriate to say anything about where suppliers sourced their lenses from as provided that lenses are genuine, this does not necessarily raise public protection issues, but we could include a commitment not to sell counterfeit lenses.

It was noted that there were different laws for online trading which online suppliers needed to be aware of.

There was an update on the consumer education messages discussed in the stakeholder steering group meeting. One area that had come up was the use of online ratings – it was felt that this would not be appropriate to include as part of any code of practice administration as sometimes consumers might rate suppliers negatively for doing the right thing (i.e. referring the consumer back to the optician).

There was discussion around how the code could be advertised. This included making use of National Consumer Week, having a credit-card size advert for people to put in their wallets with contact lens care advice. It was suggested that suppliers could be encouraged to use brief contact lens care messages on each website page (e.g. 'wash your hands', 'don't put contact lenses in tap water') so as to have a gradual education approach rather than bombarding with a long list.

[redacted] mentioned that she was on the steering committee for National Eye Health Week. In the past she has had difficulty in convincing them to include messages about contact lenses but she is happy to mention our work at the next meeting she attends. This would not stop us releasing our own message at this time.

Overview of suggestions for the code:

- will not make a misleading claim
- will actively encourage appropriate use of contact lenses (or promote safe and effective use of contact lenses)
- number of lenses supplied should be on the basis of the expiration date of the specification
- could include a reminder around when the next check-up is due.

In summary:

- the code should contain short bullet-points
- it should be implemented alongside consumer education messages
- registrants should be re-educated (via guidance)
- link in with other consumer bodies (e.g. Which?, Money Saving Expert, use of Google).

5. Implementing and monitoring the code of practice

[redacted] advised that voluntary codes of practice were usually linked to trade associations and that there was an internal disciplinary process that could fine, warn or remove those who are not complying with the code. There was often a mystery shopping element to it.

There was discussion around which trade-type bodies existed in the optical professions that could possible monitor the code of practice:

- Association of Contact Lens Manufacturers (ACLM): may not be appropriate due to the lack of infrastructure
- Optical Confederation: may not be appropriate as the British Contact Lens Association (BCLA) are not part of this group so there is no specific contact lens representation on it

- Federation of Ophthalmic and Dispensing Opticians (FODO): may not be appropriate as their membership includes the multiples

It was noted that there is no trade association for online suppliers. It was thought that there is an internet trading association but not all suppliers may wish to sign up to that.

It was felt the code should be arms-length from the GOC, as the GOC is responsible for enforcing the legislation and the code goes beyond this.

We discussed who might sign up to the code. It was thought that there probably wouldn't be large numbers signing up and that it might be more appropriate to concentrate on those with the largest market share. We will need to really be able to 'sell' the code to the online suppliers to get them to sign up to it. If there are a relatively small number of suppliers (10-15) it might not be as costly to monitor as some people thought.

It was suggested that we work out what a full cycle of supply would be so that we can think about how mystery shopping could work. This could be carried out by a small committee (3-4 people) – representatives from industry and a clinician with administrative support.

Another suggestion of an organisation to monitor the code would be the Optical Consumer Complaints Service (OCCS). The current tender for this is with Nockolds Solicitors. It may be appropriate for us to issue a tender for this work but we will need to think about funding.

We could seek funding from the Department of Business, Innovation and Skills (BIS) – they have previously offered funding from this type of work. Alternatively (or in addition) we could charge the suppliers who sign up to the code.

We could work towards the code of practice being a Trading Standards Institute (TSI) approved scheme. This might not be possible initially as the process for approval may not fit with our timescales, but it is worth trying to make our code compatible with TSI scheme principles.

6. Substitution/upgrade

It was agreed that the only circumstance in which it was good practice to substitute a lens that is different from that set out in the specification was where there was a fit match statement available from the manufacturer (or where the original prescriber recommends an alternative).

There might be a very small number of exceptional circumstances where it would be in the customer's interests to substitute (with the decision taken either by the original prescriber or a registrant working for the online supplier) e.g. when a lens has been discontinued or is out of stock and/or the specification is just out of date and the customer needs them urgently (such as for a holiday). This was not thought to be appropriate to be put in the code of practice as the decision regarding suitability will be specific to each individual. [NB We feel that this point regarding exceptional circumstances and whether or not it should go in the code of practice is worthy of further discussion at the next working group meeting.]

There was discussion around upgrades (e.g. where a new product is produced that is the same as a previous one but includes a comfort agent). This was still considered to be substitution. Lenstore's

approach to this is to advise the customer that a new product exists that might be suitable for them and refers them back to their optician.

7. Review and next steps

[redacted] thanked everyone for their input and time. The following areas were agreed for us to action or consider and return to at the next meeting:

- [redacted] and [redacted] to work up the first draft of the code of practice
- consider consumer awareness messages
- bring Which? back in to the group
- bring in someone with a marketing perspective
- consider how to engage online suppliers
- think about TSI accreditation for the code
- tendering and finances.

8. Date and time of next meeting

[redacted] advised that the next meeting of the stakeholder steering group will be on 4 March 2015 at 2pm.

Stakeholder working group on the voluntary code of practice for online contact lens supply

Wednesday 4 March, 2015, 2-4pm

GOC offices

GOC attendees: [redacted]

Attendees: [redacted]

Apologies: [redacted]

Minutes taken by: [redacted]

1. Welcome and attendees

[redacted] welcomed the meeting attendees. The minutes of the last meeting were agreed as accurate.

2. Discussion on draft code of practice

[redacted] invited comments on the draft code of practice circulated with the agenda for the meeting. Concern was raised about the first point of the code in terms of verification of the prescription, the two main concerns being that:

- a large majority of patients (estimated at approximately 99%) do not have their contact lens specification; and
- it would be too costly for online suppliers with large volumes of orders to verify a specification with the supplier (by telephone) or even to check the specification against the order made by the patient.

The following points were raised in connection with the above.

Online suppliers

- The code of practice needs to be more than just repetition of the Opticians Act 1989.
- Online suppliers need to have a way to check expiry of specifications to ensure that there is not over-supply – there was a suggestion that we could remove the requirement in the code of practice to verify the specification (although this was initially due to a misunderstanding about what the code as drafted would require), instead only checking where the patient is unsure and/or carrying out a percentage of spot-checks.
- There was concern about endorsing non-verification of a specification.
- There are a lot of off-shore suppliers and we need to ensure that the code of practice will encourage them to sign up to it.

Patients

- Patients could be asked to sign a statement to confirm that they had had an aftercare check-up in the last 12 months, although there was discussion around who would be protecting the patient in these circumstances in those cases where patients were not truthful about the date of their last check-up – it was felt that we couldn't force people to tell the truth.
- There is a parallel with ready-readers here – consumers can go out and buy these anyway and there is nothing we can do to force them to have regular sight tests, although it was pointed out that registrants who sell ready-readers are obliged to keep a register of these sales with dates of birth of patients, whereas non-optical practices do not have to do this.
- We need to decide whether we want the code to be able to evaluate the level of care provided to patients or whether it is simply a tick-box for consumers.
- The code of practice should be about protecting the public from what they don't know – a tick-box approach won't do.

Registrants

- Registrants need to be provided with guidance as to what a good specification should look like – there needs to be clarification about what an eye care professional is obliged to provide.
- It was suggested that whatever we came up with for the code of practice, we would need to be able to tolerate the same in registrants dispensing contact lenses as we would in the online suppliers that signed up to the code – the effect of this might be de-regulation.
- We have to try to persuade registrants that they need to provide specifications – this is the only workable solution to ensure that patients can buy lenses safely online.
- It was suggested we could link educating registrants about their legal obligations regarding contact lens specifications with the standards review where we are likely to provide registrants with some supplementary material in this area.
- There was a suggestion that we could also link this area to fitness to practise.
- The relationship between registrants and online suppliers is always going to be difficult – everyone needs to behave properly.
- It was suggested that we delay the implementation of the code of practice to allow time for new registrant behaviour (providing the contact lens specification) and to tie the illegal practice and standards review projects together for the benefit of patients.
- We need to deal with 'the elephant in the room' – that the vast majority of patients are not given their contact lens specification.
- There used to be a Department of Health consent form for patients to sign to consent to registrants being able to release their information in appropriate circumstances – perhaps this could be used to ask registrants to provide information within 24 hours of being requested to do so.

Other

- There needs to be collaboration across the industry, with registrants, manufacturers and suppliers working together to give the same messages.

- The free flow of information between suppliers and registrants is key here – there was a suggestion of a standard form that could be filled out by registrants whereby the registrant could sign something to say they were happy for contact lenses to be prescribed in accordance with the specification (thereby avoiding the need for telephone verification where only a copy specification is provided).
- The patient is the middle ground – online suppliers need to reply on them to input the data, provide assurance, attach a picture of the specification if they have it and ask the online supplier to verify any information they are unsure about.

[redacted] summarised that there was currently a stand-off between the professions and online suppliers. Non-compliance of one group (registrants) is driving non-compliance of the other (providing contact lenses without specifications and/or not verifying copies of specifications). As a regulator, the GOC needs to do something about patients not being given their specifications and we need to issue some sort of statement of intent about this. There are three prongs to this work that we need to carry out:

- change registrant behaviour re issuing contact lens specifications;
- online suppliers to provide contact lenses in accordance with specifications; and
- educate consumers about how to buy and wear contact lenses safely.

3. How to engage manufacturers in the code of practice

[redacted] asked for thoughts on how we engage the manufacturers in the code of practice. One suggestion was to meet with all of the manufacturers together and involve them at the beginning of this process.

It was questioned why we needed to do this, given that the manufacturers themselves will not be signing up to the code and that there was unlikely to be any resistance from them given that it would be supporting best practice for the patient. [redacted] advised that it would help to add to the weight of the code of practice and encourage online suppliers to sign up to it. It would also reassure manufacturers that we were not intending to scaremonger about contact lenses.

There was a suggestion that we could engage with manufacturers during the AGM of the ACLM. The date for this has not been set yet but is likely to be held in mid-May.

4. Process and timeline for stakeholder engagement

It was suggested that we have a multi-industry driven forum re consumer engagement. This would involve:

- industry (manufacturers / online suppliers);
- patients/consumers; and
- the press (e.g. key health journalists, social media, Which?, Money Saving Expert, Mums.net etc).

We need to think about the timeline for engagement and involve someone with expertise in marketing on the working group. We are following up on this area at the moment.

5. Arrangements for setting up and running the code of practice

It was suggested that the code of practice should be monitored via mystery shopping through a normal customer journey, as well as non-standard events (e.g. queries).

[redacted] advised that we could tender for this work and that it could be a sector-wide initiative. We could create a body to tender and oversee the contract, which could be made up of a group of people from the sector.

We need to consider if there are any brands could endorse the code.

6. Review and next steps

[redacted] thanked everyone for their input and time.

It was agreed that the GOC needed to further consider the issue of how to ensure that registrants provided specifications to patients, in accordance with legislation. It was decided to develop the code of practice as if it were the case that contact lens specifications were provided in all cases. We could consult on the code but delay implementation to give time for a change in behaviour to occur.

It was agreed that we needed another meeting of the working group before the next stakeholder steering group on 27 March. It was therefore decided to postpone that meeting (now agreed for 22 April) and to arrange a longer meeting of the working group as several people could not make the meeting scheduled for 27 March.

7. Date and time of next meeting

The date and time of the next meeting is to be agreed.

Stakeholder working group on the voluntary code of practice for online contact lens supply / consumer awareness

Thursday 14 May, 2015, 11am-4pm

GOC offices

Attendees for full meeting: [redacted]

Apologies: [redacted]

Minutes taken by: [redacted]

1. Welcome and attendees

[redacted] welcomed the meeting attendees, and in particular [redacted], who were all attending the meeting for the first time.

Apologies had been received from [redacted].

2. Minutes of the last meeting

The minutes of the last meeting were agreed as accurate.

3. Purpose of the meeting

[redacted] explained that the group had been put together to help us to brainstorm ideas which the GOC could then take away to discuss further and agree how to take forward. There will always be different views but we need to be able to challenge and support each other in these. We don't have to come up with all the answers but we can debate and generate ideas. [redacted] acknowledged that this was a really difficult piece of work and so we needed to try to come up with solutions to the problems that we will inevitable identify.

4. Engagement with the sector

[redacted] asked who the key stakeholders were that we would need to engage with the concept of the voluntary code of practice, and how we should engage them. The following stakeholders and ways to engage with them were identified (it should be noted that not all of the points raised below were the view of all those present).

- ***Optometrists and dispensing opticians:***
  - we would need some consumer research to back up why we were doing this to convince them of the need; and

- clinicians are frustrated with the issue of substitution and so this would be an area to highlight to them, together with assurance that any business who had signed up to the code but was not complying with it would be removed.

- ***Multiples:*** consumer research would be very important here to convince boards of larger optical chains that there was a compelling argument that signing up to the code of practice would be beneficial to them – they would need evidence that their customers would want the code of practice.

- ***Small/medium chains:*** the best way to engage this group would be through the Federation of (Ophthalmic and Dispensing) Opticians (FODO).

- ***Independent optical practices:***
  - this needs to be addressed in the same way as with optometrists and dispensing opticians;
  - independents are not likely to agree with the concept of the code of practice as they will not want to give out contact lens specifications so that people will buy online (although it was noted that people don't really need their specifications now anyway as they have the contact lens boxes which contain the details they need to place an order online with off-shore suppliers); and
  - the best way to engage this group would be through their insurance providers (the Association of Optometrists (AOP)), particularly if signing up to the code was part of best practice guidance.

- ***Business decision-makers / key opinion leaders:*** if this is evidenced by consumer support/request, businesses will sign up to the code. Businesses will not want to be outliers by not signing up to the code.

- ***Online retailers:***
  - market share was considered to be more important than number of online suppliers – [redacted] to advise [redacted] who the online suppliers with the largest market share are;
  - we should not assume that high street online retailers have a large share of the market; and
  - it would be very difficult to get this group in a room together and we may need to have different strategies for engaging with each supplier.

- ***Manufacturers:***
  - the largest of these are thought to be Johnson & Johnson, Alcon, CooperVision, and Bausch and Lomb;
  - manufacturers might hold the key to some of the smaller online suppliers;

- there is a dilemma for manufacturers in that they are supplying to businesses that are not complying with UK legislation as well as those that do;
- we should not over-emphasise the control of the manufacturers;
- it was noted that the supply of contact lenses in Europe might not be supplied from within the UK section of manufacturers;
- it was suggested that manufacturers might be interested in the code of practice if we could get a handle on the substitution situation; and
- we could engage with manufacturers both on an individual basis and as a group at the British Contact Lens Association (BCLA) conference if the timing is right.

- ***Professional bodies:*** many of which are already represented on the stakeholder steering or working group.

During discussion of the above, the points below were also raised.

- We need to be careful about estimating ***internet supply*** (e.g. the GOC public perceptions research found that 20% of people were buying contact lenses online but this could be an over-estimate for true internet supply) – many customers would consider they were buying their contact lenses online but they are doing so through a high street chain with repeat purchases over the internet.
- The idea of ***verification*** – it was suggested that registrants would appreciate clarity over the regulations around verification. When the regulations were introduced in 2005 there was no lay interpretation given to registrants and so there is confusion over this point. Legal advice sought by some business registrants has placed different interpretations on what was meant by the original of a specification.
- What are the ***benefits*** of signing up to the code of practice? Examples were patient safety within the industry and a marketing tool for online suppliers (who will sign up if their customers want them to), particularly if the logo was endorsed.
- ***Endorsement of the logo*** was discussed. It was suggested that it could be endorsed by:
  - Which? – some members cautioned against this idea as this was seen to be too political and very demanding;
  - the Trading Standards Institute (TSI) – although not necessarily in the beginning stages of implementing the code; this is something we could work towards; or
  - the MHRA – [redacted] did not feel that the MHRA had the right profile and there were restraints around what they could do. They can give guidance around buying contact lens (e.g. ensuring the product is CE-

marked) but cannot be seen to be endorsing particular online suppliers. [redacted] will look into whether it would be possible to point consumers to online suppliers that sign up to the code.

- We need to be careful about how we communicate to registrants that there is a legal requirement to issue ***contact lens specifications*** – we should separate it out from this piece of work. [redacted] explained that the GOC would be seeking to clarify legislation through the introduction of the new standards of practice.
- It was noted that ***counterfeit lenses*** were not considered to be an issue.
- We need to think carefully about when to introduce the code of practice – we have only one chance to get it right. We need to work out when the ***key communications dates*** would be.
- We need to ***engage with stakeholders prior to the consultation period*** so that they feel engaged in the process, particularly the key manufacturers, the multiples and the online suppliers with the largest market share. This engagement will then help to inform our consultation questions. We need to be clear about what we're asking and whether we're just looking for general feedback or level of importance on a scale of one to ten.
- We could look into ***sign-posting advice*** given by other websites such as NHS Choices, which could make suggestions for the types of websites to buy contact lenses from. NHS England has recently started a health apps library which guides patients to apps to manage their health that have been reviewed by the NHS. The Better Regulation Delivery Office (BRDO) is an example of a sign-posting website (https://www.gov.uk/government/organisations/better-regulation-delivery-office).
- It was noted that there will be a self-policing element to the code of practice. The sponsor will need to show how online suppliers complied with the code and that they would be removed if they did not comply. It was suggested that any ***complaints*** to a code sponsor were more likely to be about not supplying contact lenses to a customer, rather than any other issue.
- It was suggested that the code of practice should include ***advice about how to complain*** (e.g. it could point them to the Optical Consumer Complaints Service) and appropriate re-dress mechanisms for unsatisfied customers. The idea of certified shops was discussed where there would be a pop-up message at the end of a transaction to make it clear to customers about what they could do if they are unhappy with their purchase. The law around consumer rights is changing and the Department of Business, Innovation and Skills (BIS) is currently deciding how to implement the change in law – it is thought that there are already numerous bodies in existence that provide dispute resolution services that an online supplier could sign up to.

- It was noted that the numbers of people wearing contact lenses have not actually increased over the last few years or so because of the high number of drop-outs from those people who choose to stop wearing contact lenses.

5. Consumer awareness

[redacted] opened this section of the meeting by summarising some work carried out by the Competition and Markets Authority (CMA) related to higher education consumers, which they did not have a budget for. They prepared some guidance on how consumers could complain about higher education and then produced a sixty second summary document together with adverts giving examples of areas that students should look out for. All of these materials were produced internally at no cost (other than staff time) and were shared with partner organisations such as the Universities and Colleges Admissions Service (UCAS). They also wrote a blog article on the Which? website and carried out a live chat on a student forum. Following a tweeted message by UCAS about the campaign, the CMA received 500,000 hits on its website (having received 10,000 prior to this). This shows what can be done through consumer awareness raising even when there is no money involved.

There was discussion around the need for some ***consumer research*** about the demographics of who buys online. One of the multiples considered that online consumers were largely consumers in their 20s who were concerned about cost and convenience, and not overly concerned about their health. This was not considered to be the demographic profile of all online consumers – anecdotal evidence suggested that a lot of customers were older. It was suggested that we carry out research into:

- contact lens consumers already shopping online; and
- contact lens consumers who do not shop online.

It was noted that existing research from one of the multiples had shown that risk profiles of consumers were very different – some would never buy their contact lenses online as they see it as a health product and others do not see any difference between buying contact lenses in person or buying contact lenses online given that they come in the same box. This is a big challenge for us to investigate, particularly given that we do not have a huge amount of resource to put into this.

It was suggested that we could do a telephone dip survey, which would be targeted and quick e.g. YouGov carry out surveys at £300 per question for a consumer survey of approximately 2,000 people. We might need a range of methodologies to get good insight into why people do and do not buy online e.g. focus groups or interviews. It was also suggested that we might be able to access Lenstore's database to carry out a Survey Monkey type survey. It might be difficult to access databases held by the multiples as these could be subject to Data Protection Act restrictions if customers have opted out of communications other than reminders. It

was noted that we needed to distinguish properly between true online sales and those that are effectively repeat purchases from one of the multiples – Lenstore is now a blend of both since its ownership by GrandVision BV (the parent company of Vision Express) in December 2013.

There was discussion around what the key difference is between those who shop online and those who do not. One of the key differences in the buying experience was considered to be the absence of a health professional giving aftercare advice in person. The crux of the challenge was felt to be both substitution and verification of specifications (which a lot of consumers do not have access to). Some customers are actually driven online by the verification laws that business registrants are complying with, because they do not want to wait for the business registrant to verify the information with or seek the information from their prescribing eye care practitioner.

It was suggested that ***National Eye Health Week*** in September might be a suitable partner organisation for our consumer awareness raising campaign, although it might be too late for this year. It was felt that we should not rush our campaign as we need to get it right. National Eye Health Week has the benefit of being a month before Hallowe'en where there is often press about problems experienced with zero powered contact lenses. We could develop a case-study but we do not want to scare people into not wearing contact lenses by concentrating on the negatives, so we would need to be careful about how we did this.

It was suggested that we might want to consider what other products we could align this campaign to e.g. wearing seatbelts or bicycle helmets. We could then see if it would be possible to link ourselves into another campaign for our benefit.

It was noted that not all consumers would necessarily engage with social media, particularly those who are not in their 20s.

The MHRA has received reports from consumers that they had either not been given aftercare advice or were not fully aware of the potential serious consequences of not following it.

Any awareness raising campaign needs to give clear advice to consumers about how to buy contact lenses safely online e.g. check that the business has a registered optician as part of its team.

At this point the meeting was stopped for lunch and [redacted] left the meeting.

6. Update on the voluntary code of practice

[redacted] updated the group on the ***feedback from the stakeholder steering group*** held on 22 April 2015, summarised in the draft Council paper supplied as an enclosure to the agenda. The main point for consideration was that as currently drafted, GOC

business registrants would not be able to sign up to the code as it allowed non-compliance with UK legislation. There was also a lot of discussion around the purpose of verification and whether there was any way that the law around this could be relaxed (if not changed).

[redacted] provided ***feedback from the Council meeting*** held on 13 May 2015. Council recognised the scale and complexity of the task at hand and appreciated the efforts of the working group to date. Much of the discussion was around the absence of contact lens specifications and how easy it was to order contact lenses online without these, as well as the occurrence of substitution. Key points from Council included:

- educating registrants and patients around contact lens specifications;
- softening the wording of the draft code of practice in some places;
- an understanding of how aftercare advice is considered to be critical; and
- educating patients about safe and effective use and wear of contact lenses.

Council did not give any comment on the proposed options following the stakeholder steering group's feedback, the issue of the code operating beneath the legislation, or any kind of registrant 'amnesty' around the requirements of the legislation with regard to verification.

The key issues for this group to discuss were considered to be:

- the applicability of the code of practice to UK business registrants;
- the four options proposed in the Council paper to address feedback from the steering group; and
- the need for a definition of verification.

It was suggested that what was missing from the code of practice was reference to verifying the contact lens specification. It was noted that verification is not currently defined in the law and so there are many different interpretations. It was then suggested that introducing verification into the code of practice would not be of any benefit – verification does not make things any easier and it would confuse consumers who likely do not know what a specification is or what verification means. In any event, there is no point in adding verification to the code of practice until consumers have their contact lens specification.

It was noted that when the new standards of practice are introduced, the GOC will be giving registrants advice about the legislation around contact lens specifications. It was also suggested that it would be helpful if the GOC could define the law around verification. Some people present felt that a change in registrant behaviour would take around six months after any guidance was issued, whereas others felt it would take longer than this.

It was felt that the law around verification is essentially 'killing' businesses and/or driving business off-shore. The working group felt that ***the law around verification is not fit for purpose*** and needs to be changed at the earliest opportunity. There is also a lack of clarity around 'supervision' and 'general direction' and this has led to some companies (even in the UK) essentially acting as 'box shifters' of contact lenses without appropriate involvement of a registrant.

There was a challenge as to why any business registrant would sign up to a code that legitimised non-compliance with UK legislation. A possible way to get round this would be to have either a two tier code or one code for registrants and another for non-UK online suppliers. These were not felt to be viable options – it would create confusion for consumers and you would still have the issue of the code legitimising non-compliance with legislation.

We need a middle ground between compliance with legislation and making things safer for those consumers who are buying contact lenses online from non-UK suppliers. It was suggested that the only way we could make the code of practice palatable for business registrants would be to remove points 1-3 of the code that referred to supplying in accordance with or not having a contact lens specification. We discussed what would be lost by removing these points from the code:

- a contact lens specification expiry date / date of last appointment with an eye care practitioner – this could be combatted by educating the consumer about the importance of regular aftercare and advising not to order contact lenses if you have not had an eye care appointment in the last 12 months; and
- a date after which contact lenses could not be supplied – we will need to consider how this could be addressed, but again we could suggest limiting supply to no more than a year and educating the consumer about the importance of not ordering contact lenses beyond the date of their next aftercare appointment.

It was agreed that revising the code of practice along the lines suggested would enable business registrants to sign up to it and would give businesses comfort, especially around substitution. It was also noted that there had been discussion in the stakeholder steering group meeting about the BCLA holding a database of contact lens types and which could be substituted (on the basis of fit-match studies by the manufacturer of that brand) – this would be a positive for registrants.

It was suggested that some online suppliers are sending out ***marketing emails*** advertising new/different types of contact lenses that could effectively lead to consumers self-substituting by ordering these lenses without seeing an eye care practitioner. It would be helpful if something could be added to the code to stop this from happening without clear guidance to consumers that they need to see an eye care practitioner before changing lenses.

We need to get to the point where businesses will ask themselves why they would not join. The commercial benefits could be huge, particularly as more and more people are likely to buy online.

Given that the code of practice would be a living document, it could change over time as practice around the issue of contact lens specifications changes. It could slowly bring up the level of practice found outside the UK, to bring it in line with that of registrants.

There was discussion around whether the code of practice should be applicable for ***zero powered contact lenses***. Under UK legislation, zero powered contact lenses cannot currently be supplied online as they require the supervision (physical presence) of the registrant. It was suggested that the code stay silent on zero powered contact lenses given that specifications are not given out for zero powered contact lenses.

There was concern around the ***fee*** for some businesses and whether this would be too high for some to consider signing up to – even £500 would be a significant sum that some businesses would not feel was warranted. It was suggested that the manufacturers might be able to contribute to the funding of the code, particularly in the first year or so when numbers signing up would be unknown.

Action points

1. [redacted] to advise [redacted] who the online suppliers with the largest market share are.
2. [redacted] will look into whether it would be possible for the MHRA to point consumers to online suppliers that sign up to the code.
3. [redacted] to consider consumer research suggestions.
4. [redacted] to remove points 1-3 of the current code of practice that referred to supplying in accordance with or not having a contact lens specification and consider if the points lost could be incorporated in other parts of the code.
5. [redacted] to add a point to the code of practice around marketing emails.
6. [redacted] to remove reference to zero powered contact lenses in the code of practice.

Stakeholder working group on the voluntary code of practice for online contact lens supply / consumer awareness

Wednesday 17 June, 2015, 10am-1pm

GOC offices

Attendees: [redacted]

Apologies: [redacted]

Minutes taken by: [redacted]

1. Welcome and attendees

[redacted] welcomed the meeting attendees, and in particular [redacted] who was attending the meeting for the first time.

Apologies had been received from [redacted] and [redacted].

2. Minutes of the last meeting

The minutes of the last meeting were agreed as accurate.

There was discussion around the following points:

- that establishing the age of consumers buying online was not the key purpose of any consumer research (with the view that multiples were likely to have a demographic that was different to those buying from online-only suppliers);
- [redacted] was not clear where the idea for a two tiered version of a code had come from and why it had been in the Council paper – it was explained that this had been suggested by the GOC (not by the working group) to try to address the concerns of the steering group. This idea had been discussed at the last working group meeting and was not thought to be workable; and
- it was not clear why zero powered contact lenses had been removed from the code as this was considered to be a missed opportunity – it was explained that it had not been felt possible to include these in the code as these could only be supplied 'under the supervision' of a registrant (and therefore cannot legally be supplied online as the registrant must be on the premises and in a position to intervene) and did not require a specification, but we agreed to look at this further to see if it would be possible to make it applicable for zero powered contact lenses also.

3. Update on latest version of the voluntary code of practice

[redacted] presented the current version of the code of practice (dated 11 June 2015) that had been distributed with the minutes and explained the reasoning behind the changes made at the last working group meeting (for the benefit of those who had not been present) and the feedback we had received from the GOC's Senior Management Team (SMT) since our last meeting. It was agreed that the re-phrasing of the code into 'We will..' or 'We will not…' was helpful. We discussed each of the six points in the code.

Point 1: The point raised by SMT was not felt to be an issue – it was considered that the British Contact Lens Association (BCLA) would always keep their guidance up to date with current practice and that there was agreement in the industry about what good contact lens advice looks like.

Point 2: [redacted] advised that he would propose some alternative wording that would cover all relevant legislation without referencing particular ones that might become out of date.

Point 3: It was suggested that we need a definition of what 'regular' aftercare means including clarity on how long a contact lens specification should last for, although there was concern that this might not be possible as clinicians need to be able to use their professional judgement. It was suggested that this issue could be addressed through the GOC's standards review.

Point 4: It was agreed that we should remove this point as it no longer made sense given that we had previously removed the points around the expiry date of a contact lens specification and date of last aftercare appointment. In addition, it would not be possible for online suppliers to identify what a 'one year supply' would be given that some customers wear their lenses only a few times a week or month and others wear them every day. It was agreed that we could add something to point 3 to ask customers to provide assurance that they would not order supply beyond the expiry date of their specification (if available).

Point 5: Feedback from SMT suggested that there was nervousness around a perception that this point could be seen as favouring one part of the industry over another. Some members of the working group felt strongly that these points around substitution must remain as they are. It was also felt that points 5b and 5c must be included as technically they are substitution (in law) even though they are the same product material and from a consumer perspective the products would appear to be different (e.g. different packaging and product name) – it was therefore agreed to add to the explanatory notes to further explain (for the benefit of customers) what this means. It was agreed that we would add to the introduction of the code to point to the risks to the public in relation to the online supply of contact lenses and substitution identified by Europe Economics in their research. This would highlight

the public protection rationale for this aspect of the code. It was felt that these points as worded in the code would be acceptable to the profession.

Point 6: It was felt that although the sentiment of this point needed to be included, it needed to be re-worded to be phrased more positively e.g. first address informing the customer and then mention the importance of a further fitting. In particular the word 'encourage' was not considered to be helpful.

[redacted] advised that we should not worry too much about making the code of practice understandable to the public – it is those signing up to the code that need to understand it and the guidance for consumers can explain to the public how they will be protected by the code and how to complain. It was noted that this code is much shorter and easier to understand than a lot of other codes of practice that exist.

4. Update on consumer research

[redacted] advised that the GOC was considering carrying out some research into contact lens wear (as part of our illegal practice strategy) and to look into whether the public would be reassured by the creation of a code of practice. The general consumer research would give us some benchmarking data to track changes following implementation of the code of practice and give us some data on how often people buying online have sight tests and/or aftercare appointments.

It was noted that the multiples and manufacturers would have data on the demographics of customers buying their contact lenses.

It was noted that ultimately we would want figures on whether a code of practice had decreased the rate of infections in contact lens wearers but this would be very difficult and costly to measure.

It was noted that the research into whether a code of practice would give people more comfort to buy online would be hypothetical in nature. It was suggested that we might want to carry out a literature review to see if other industries had investigated the impact of a code of practice.

It was noted that the logo associated with the code of practice might be good for encouraging registrants to provide contact lenses online.

It was agreed that the principal reason for the research would be to allow us to track consumer habits re buying contact lenses online and assess whether a code of practice might increase likelihood of the public buying contact lenses online safely. All to send comments to [redacted] if there are any areas that would be helpful to include within the research.

5. Planning for stakeholder engagement with the code of practice

Name of stakeholder	Key individual(s)	Key message(s) / objective(s)	Comments
MANUFACTURERS			
Association of Contact Lens Manufacturers (ACLM)	[redacted]	• Need them to be supportive of the code – encourages safe use of their products • Can contact the GOC directly if they have any queries • Positive messaging/assurance is important – the code is not designed to scare people off wearing contact lenses • Potential to grow their business	• Engage manufacturers through the ACLM (approx. 15 members covering 99% of contact lens wearers in the UK) • Manufacturers are responsible for the quality of their product and can supply to any company with a registrant on board, but there can be no restrictive trading i.e. we cannot ask them to only supply to those who have signed up to the code • They will be concerned about whether they will be asked to contribute any costs
PROFESSIONAL BODIES			
Association of British Dispensing Opticians (ABDO)	Chief executives	• Need them to encourage support for the code among the profession and encourage members supplying contact lenses online to sign up • Conversation around who could sponsor the code so that we have some firm options by the end of the consultation period	• Engage through meeting of chief executives of optical bodies (includes the Optical Confederation as well as the GOC, College and the BCLA)
Association of Optometrists (AOP)			
British Contact Lens Association (BCLA)			
College of Optometrists			
Federation of Manufacturing Opticians (FMO)			
Federation of (Ophthalmic and Dispensing) Opticians (FODO)			
Optical Confederation			
Association for Independent Optometrists and Dispensing Opticians (AIO)	Chief executive	• The code will raise awareness about wearing contact lenses safely, including the need for regular aftercare and so will be beneficial to their members	

Name of stakeholder	Key individual(s)	Key message(s) / objective(s)	Comments
Royal College of Ophthalmologists (RCOph)	[redacted]	• Inform about the code of practice and why we are doing this	
PROFESSION			
British Contact Lens Association (BCLA)	[redacted]	• Encourage members to sign up to the code	
Multiples		• Encourage multiples with online business to sign up to the code – consumer research will assist here	
GOC individual registrants		• Encourage registrants with online business to sign up to the code – beneficial to business	• Contact directly as part of consultation
GOC business registrants		• Encourage registrants with online business to sign up to the code – beneficial to business • Value of chair time (charge more appropriately) – driving patients back into practice • Data to show contact lens sales online are growing and you should use this opportunity to gain loyal customers and sign up to the code	• Contact directly as part of consultation
ONLINE SUPPLIERS			
To be advised		• Encourage to sign up – it will increase sales and customer loyalty, as well as public confidence in your brand	• Need to consider UK vs non-UK online businesses • Online suppliers will want to know how much this will cost them and how they would need to alter their business practices/website to sign up

Name of stakeholder	Key individual(s)	Key message(s) / objective(s)	Comments
		• Message for non-UK suppliers – our market is young but is growing quickly – you need our logo to get UK customers	• Suggest begin the approach now, so that we can slowly build up support and make the case for change • The way into the UK base is through the registrant
OMNI-CHANNEL SUPPLIERS			
Specsavers, Vision Express, Lenstore, Asda, Tesco		As above with online suppliers	
Small chains with online business			
Individual practices with online businesses			
Key opinion leader	[redacted]		• [redacted] created an app and practice management software which makes it easy for individual practices to have an online business
PRESS			
Optician and Optometry Today		• Positive publicity about the code of practice and what we are trying to achieve	• Requires careful handling – better to do an interview (so that we can respond to questions) rather than just a press release
CONSUMERS			
Consumer representative bodies e.g. Which?, Money Saving Expert		• Informed consumers (e.g. aftercare) – code improves safety and provides assurance	• Aim of the code: that everyone buying contact lenses online looks for the logo • Two groups of consumers – those that buy contact lenses online and those that do not

During discussion of stakeholder engagement the following points were made:

- whether we could make the code of practice available to suppliers of contact lenses who were not operating online as this would be less confusing to customers and would mean that registrants who do not have an online business could benefit from the code:
    - it was generally felt that we would not be able to make the code appropriate for non-online suppliers until we had been able to address the issue of registrants not supplying contact lens specifications and that perhaps we ought to add to the code that the logo is only for use online so that high street practices with online businesses cannot display the logo in their shop windows;
    - it was also commented that this was not the remit of the group – we had been asked to devise a code of practice for online supply;
- whether we had the name of the code right – a code of best practice was suggested;
- throughout the consultation the GOC needed to make the link between the law and the code and to explain how we have gone about developing this with stakeholders;
- the GOC will take the lead on engaging with stakeholders throughout the consultation but would appreciate support from members of the working group within their own organisations; and
- it was suggested that we might wish to make reference to Phil Morgan as having been involved in this work during the early stages to give it further credibility.

6. Advice and guidance for consumers on contact lenses

[redacted] felt that we did not fully understand the demographics of contact lens wearers which would be key to deciding how to disseminate any guidance. [redacted] considered that the question should be *how* we deliver the consumer information, not *what* it should be, as all the guidance out there tends to be generic and good. The AOP and ABDO both refer to the BCLA guidance. The College of Optometrists recently issued their own guidance on contact lenses.

[redacted] showed the meeting attendees the current BCLA leaflets – *Buying contact lenses*, *Wearing contact lenses* and *Looking after contact lenses*. It was felt that these could possibly be combined, although one of the leaflets went into a lot of detail about the different types of lenses available, which may be too much detail. It was noted that there is robust peer reviewed research about what has been included in the leaflets – the contact lens industry is aiming for consumers that are happy, healthy and more compliant.

We need to consider what media we should use to promote the guidance and we need to have something to account for all types of consumers e.g. a bank of tools

such as paper and online instructions, downloadable and printable leaflets available online, YouTube videos showing contact lens insertion/removal. Research may help us to identify this.

This is an area where we are going to need some marketing expertise to support us. It was suggested that this was carried out by someone neutral (i.e. not within the industry) and perhaps recruited from outside of London to get the best deal.

[redacted] indicated that the MHRA would be willing to share some hints and tips around previous marketing campaigns that they had carried out.

[redacted] advised that Public Health England had a People's Panel which they use to test out documents going into the public domain.

7. Next steps

[redacted] explained that the next steps were as follows:

- feedback to the stakeholder steering group on 9 July 2015;
- if agreed, present the code of practice to Council on 29 July 2015;
- if agreed by Council, consult on the code of practice in between August and mid-October;
- consider feedback and take a final version of the code of practice to Council in November 2015; and
- agree and finalise who will run the code of practice with the aim of implementation by April 2016.

It was agreed to hold our next meeting in mid-September 2015.

8. Any other business

There was no other business and the meeting was closed at 1pm.

Action points

1. [redacted] to discuss with [redacted] who the online suppliers with the largest market share are.
2. [redacted] to update the code of practice as outlined in section 3.
3. [redacted] to look into whether reference to zero powered contact lenses can be put back into the code of practice.
4. [redacted] to progress consumer research suggestions.
5. All to feedback to [redacted] on areas for consumer research.
6. [redacted] to agree a definition of 'fit-match' with manufacturers.
7. [redacted] to consider stakeholder engagement suggestions and put together a plan for the consultation.
8. [redacted] to share [redacted] hints and tips re marketing campaigns.

Stakeholder steering group on contact lens supply

Thursday 9 July 2015, 11am-2pm

GOC offices

GOC attendees: [redacted]

Apologies: [redacted]

Minutes taken by: [redacted]

1. Welcome and attendees

[redacted] welcomed the meeting attendees to the second meeting of the steering group on contact lens supply. Apologies were received from [redacted] and [redacted] (who had sent comments by email).

The minutes of the last meeting were agreed as accurate, subject to one amendment to the last paragraph on page 2.

2. Report of the stakeholder working group

[redacted] reminded attendees about the background to this work, with an emphasis on looking after and protecting the consumer. The legislation is out of date in this area and in an ideal world we would change it, but that is not going to happen in the near future. No other regulator in the world has attempted to tackle this problem, but following the research findings from the Europe Economics report on illegal practice, doing nothing is not an option for a responsible regulator. A code of practice is usually an aspirational standard above the law but we are in a grey area in optics – this is not a normal context.

[redacted] explained that the working group met in June 2015 to review the feedback from the steering group and from Council and SMT. Council particularly noted non-compliance of registrants in handing out contact lens specifications to their customers. What we need to decide now is whether we can live with the code and sign up to it, in the circumstances in which the world of optics is operating. The inclusion of substitution has generally been received positively. We have had some great debate in the working group around what to include in the code. At our last meeting we began to look in more detail at stakeholder engagement and came up with some key messages and an engagement strategy.

[redacted] gave a summary of the key points from the report of the working group (the code of practice, stakeholder engagement and consumer awareness), emphasising in particular the issues surrounding zero powered contact lenses and whether the code could be extended to all suppliers of contact lenses, not just online.

3. Feedback on the code of practice

[redacted] suggested that we needed to make some decisions around how simple we keep the code of practice – it is not possible to deal with everything in it. We see it as a living document. Legislative change is very unlikely to happy in the near future but as legislation and practice changes over time, the document can be updated. [redacted] invited feedback from the group.

[redacted] said that he could envisage the ideal situation in around five years' time, but given we are not there yet this needs to be an easy first step that makes sense for the patient, the business and the registrant. We may need compromises at this stage but if we know where we want to get to and how to get there, this will be a positive step as a 'light touch' code of practice. If the requirements of the code are too onerous, we will not get anywhere as no one will sign up. [redacted] suggested that we should not get hung up on small points, for example, no lenses beyond a year. We need to keep horizon scanning and looking to the future.

[redacted] suggested that this stakeholder group is a really useful forum and that it should continue on a regular basis, to review the code. When the code is published, we should mention its ongoing review.

The following specific feedback on the code was given:

- Purpose: this should include reference to those members of the public who choose to purchase their contact lenses online.
- Point 1: it was suggested that we should not specifically mention the British Contact Lens Association (BCLA) and should instead refer to the professional bodies, although it was also noted that this could be confusing to refer to different sources of information.
- Point 2: there was a suggestion to incorporate something about zero powered contact lenses in this section but it was decided that this would not be appropriate.
- Point 3: we discussed that this was about complaints to the online supplier and agreed to add this to make it clearer.
- Point 4:
    - 4c 'not ordering on behalf of someone else' – it was agreed that it could be legitimate to do so in certain circumstances (e.g. someone who cannot use a computer) and therefore this would need some re-wording;
    - 4d – 'regular aftercare appointments' to be amended to ' aftercare appointments at intervals as directed by your eye care practitioner';
    - 4e – it was agreed that 'contact lens advice' should include reference to the online supplier, manufacturer and the eye care practitioner;
    - 4f – this should include reference to 'within the last two years'; and
    - 4h – it was agreed that this sentence should include reference to a two year supply rather than mentioning the contact lens specification.
- Point 5:
    - it was agreed that we remove reference to a fit-match study and replace 'requested' in some places with 'prescribed'; and

    - it was suggested that we might wish to add reference to a tinted lens so as not to present an unreasonable barrier e.g. a tint that had been applied to a lens that had been prescribed by an eye care practitioner.
- Point 6: replace 'see' with 'consult' and tighten up the wording around the contact lens fitting.
- Point 7: as currently worded this looks like it has been tagged on at the end. The group were reluctant to see it disappear and suggested that we might want to look at re-wording it. It was felt useful to explain why we were including it i.e. mention the Opticians Act.
- Explanatory notes: it was suggested that we move the first paragraph of the explanatory notes to the purpose section on the first page

During discussions about 4f and 4h (in relation to restricting sales to a two year supply), it was noted that it is possible to get the technology to 'cap baskets' on online sites but it was currently felt that it would be too difficult to make this a requirement of the code.

It was noted that all of the assurances provided in point 4 of the code would not need to be verified by the online supplier – these act as a warning system for customers in areas where it would be too difficult for the online supplier to be able to verify. These are essentially the 'red traffic lights' that we are alerting people to and if they choose not to take account of the warning, there is nothing we can do about that.

During discussions there was a suggestion that the guidance for consumers should refer to buying from a GOC registered UK supplier or an online supplier signed up to the code e.g. 'if you choose not to buy contact lenses from your (regular) eye care practitioner…'.

With regard to fit-match studies, it was suggested that we could have a body to sign off fit-match studies (or at least to confirm that the principles of a fit-match study have been followed) e.g. ACLM/BCLA. It was suggested that people might not want to take this on as they would not want the responsibility.

4. Feedback on stakeholder engagement

[redacted] said that overall he thought the code of practice was excellent. He very much saw it as a first code of practice that will develop over time. He felt that it was pragmatic and that the code and the law were mutually exclusive – the code works as an addendum to the law. With regard to stakeholder engagement, he felt that we had broadly identified the right stakeholders to engage with and that it was important that manufacturers were engaged.

[redacted] said that we need manufacturers to encourage suppliers to sign up (and to identify who they are). [redacted] suggested that we ask manufacturers what they would be willing to do (to encourage sign-up to the code of practice) to ensure patients are using contact lenses safely. We need to encourage them to promote it and give them a reason to believe that this is the right thing to do and that it will be easier for consumers to wear contact lenses safely.

[redacted] said that in terms of registrants, we need to approach this carefully and make sure that registrants are going to be seen pivotal in the code of practice. [redacted] said that the code of practice could be seen to legitimise non-registered suppliers and so we need to stress the importance of regular aftercare with an eye care practitioner. In terms of presenting it to the profession we need

to focus on the positive points like substitution. [redacted] said that there was a new AOP Policy Committee and that he would invite the GOC along to this to discuss the code of practice.

[redacted] said that we would create a core presentation with key messages/benefits of the code of practice to be presented to different audiences

[redacted] said that everything in the code refers you back to the eye care practitioner, which is a good thing for registrants. [redacted] said that she liked the use of the term 'pivotal' suggested by [redacted]. We also need to dovetail in the contact lens specification issue. [redacted] advised that we would deal with this separately through the standards review. It was suggested that registrants might think they are being given a stick (the contact lens specification) but the carrot (the code of practice) is being given to the supplier. [redacted] said that we will explain in our consultation document that we cannot do what we want to be able to do (e.g. we cannot get all online suppliers to comply with UK legislation) and that instead, our proposals will seek to improve the practice of these suppliers for the benefit of patients and registrants.

[redacted] said that there we need to explain that there are approximately 750,000 people buying online and we need to do what is right for them – we cannot wait three parliamentary cycles. We then need to go on to explain what we can do and emphasis that it is a living document that will change over time.

5. Feedback on consumer awareness

[redacted] said that anything we can publicise online would be beneficial e.g. Money Saving Expert (MSE), www.mumsnet.com.

[redacted] said that there were some great resources already around the table and the information should be targeted. [redacted] questioned whether we needed to do any more research as she felt that we have the information already and that we should be asking the manufacturers for this information.

[redacted] suggested that we need to start working out who else might start buying contact lenses online in the future e.g. 15-16 year olds now, so www.thestudentroom.co.uk might be a good place to publicise.

[redacted] said that 'Mumsnet' and 'Studentroom' charge a fortune to access their sites. [redacted] suggested that we could make this a case study about how the digital world is changing e.g. digital Britain and how we are dealing with it and keeping pace with technology. [redacted] suggested contacting [redacted]. [redacted] said that MSE might not be the best place to concentrate resources as it relates to less than one per cent of contact lens sales.

[redacted] suggested that we could think about contacting Google and asking if they would be interested in publicising something from a patient safety aspect.

There was a brief discussion about who would manage the code. [redacted] said that the GOC cannot do this because of the link with the legislation and will therefore need to pass the code over to another organisation at an appropriate time. We will also need to think how the GOC will feed into the code of practice on an ongoing basis after it has been handed over. Several people around the table

suggested that the BCLA might be a suitable body to sponsor and manage the code of practice. We will need to explore options during the consultation.

6. Any other business

There was no other business. [redacted] thanked everyone for their input and time.

7. Date and time of next meeting

[redacted] advised that the next meeting of the stakeholder steering group had not yet been set but was likely to be in mid-October, after the consultation period had finished.

Stakeholder working group on the voluntary code of practice for online contact lens supply / consumer awareness

Thursday 17 September, 2015, 10.30am-12.30pm

GOC offices

Attendees: [redacted]

Apologies: [redacted]
Minutes taken by: [redacted]

1. Welcome and attendees

[redacted] welcomed the meeting attendees, and in particular [redacted] who was attending the meeting for the first time. [redacted] explained her background as a [redacted].

Apologies had been received from [redacted] and [redacted].

2. Minutes of the last meeting

The minutes of the last meeting were agreed as accurate.

[redacted] updated the group with an example fit-match statement as below:

Where the manufacturer has recommended:

- *a replacement lens for a discontinuation;*
- *a better version of an existing product; or*
- *a lens which has evolved into a better format.*

This must be substantiated by the original manufacturer with robust clinical data. Substitution in these circumstances would not necessarily require review by an eye care practitioner.

[redacted] reminded the group that the ultimate goal was patient safety. This piece of work is about signposting, educating and informing consumers of contact lenses.

3. Updates

Council on 29/7/15: [redacted] advised that Council had been supportive of the code of practice and had not requested any amendments before signing it off for public consultation. There had been some concern about what we do if no-one in the sector came forward to sponsor the code. We explained that we hoped there would be some interest during the consultation period.

Press coverage: [redacted] advised that press coverage so far had been generally positive. The British Contact Lens Association (BCLA) had put out some positive coverage and intended to do so again before the consultation closed.

There was concern from two members of the group that we were producing something that only a few will be able to sign up to and wondered if it could be made available to all businesses providing contact lenses, not just those selling online. The GOC felt at this time that the code should only be for online suppliers as otherwise the costs of managing it would be too great. We could look to extending it in the future. For now, we will need to concentrate on educating the public about how to buy and wear contact lenses safely.

It was noted that the best opportunity to provide information to a contact lens wearer is when someone is fitted for the first time. The next time (for online customers) is when they use a search engine to find contact lenses to buy. The third time is the online website they use to buy contact lenses.

Stakeholder meetings: [redacted] advised that we still had several meetings with the professional bodies coming up in the next week or so. [redacted] and [redacted] had attended a meeting with the Federation of (Ophthalmic and Dispensing) Opticians (FODO). The message from them was to keep the code simple and low cost. We should be 'nudging' consumers in the right direction. There was also encouragement that we should get in contact with EUROMCONTACT and that we should check that the wording on substitution was watertight. [redacted] also offered to check any comments we might receive about anti-competitiveness.

4. Code of practice

[redacted] challenged the group to come up with the simplest process by which someone could operate the code and with no money available. It was suggested that we could:

- mystery shop the online supplier – in particular we could try to do something that you should be able to do e.g. put in a date of birth for someone under 16;
- test content on the website and test the order process;
- require suppliers to complete a self-assessment form which could ask suppliers to direct us to the parts of their website where relevant information is (Lenstore have their own audit form and there is an audit form on Quality in Optometry);
- we could require the self-assessment form to be put on the supplier's website;
- test purchase over the telephone e.g. if a child runs out of contact lenses or a specification has expired;
- mystery shopping once a year should be enough;
- monitor mailing lists in between mystery shopping test purchases;

- there should be differentiation in our mystery shopping between first-time and returning customers;
- the audit process needs to be weighted and whoever carries it out needs to understand the process; and
- we could publish the findings of each audit on the sponsor website.

We need to decide what the consequences of non-compliance are e.g. removal of the logo straight away, or a warning letter with a period of time to allow for compliance (the latter option was preferred).

There was discussion about whether we should only test the website for compliance if the code sponsor received a complaint, but this was not thought to be appropriate. A complaint could trigger an extra review on top of the annual review.

There was discussion about whether the logo should be dated. It was suggested that it should not, but rather just link through to the sponsor website which would have an up to date list of organisations. [redacted] said that he could provide information about copyrighting the logo.

It was suggested that a small working group is put together to come up with an audit process.

Actions:

- [redacted] *to set up a small group together to come up with a self-assessment template.*
- [redacted] *to provide copyright information re the logo.*

5. Consumer engagement

It was suggested that we needed to concentrate our engagement with consumers on particular moments in time. It is difficult to get everyone from the beginning so you need the industry to support this. It was noted that there are approx. 4 million people wearing contact lenses (out of a population of approx. 38 million people with vision correction needs) and approx. 500,000 contact lens wearers buying online. It was suggested that we need to map these customer journeys.

There are two main areas when there are opportunities to give people information about wearing contact lenses safely. These are:

a. *First fitting of contact lenses:*
   - people tend to come back within 1-2 years of this first appointment;
   - they need to understand the difference between their sight test prescription and their contact lens specification;
   - it would be helpful for them to have a leaflet to take away with them – it needs to be engaging;

- the leaflet could link to NHS Choices.

b. *Information given when lenses are received:*
   - needs to include safety messages on inserts or delivery notes about regular eye tests, 'no water' graphic, code of practice logo;
   - ideally we need the top five safety messages on the delivery note;
   - we could consider alternative language used by the Public Health 'nudge unit'.

[redacted] advised that consumer research suggested that consumers are not receptive to information at the point of sale. He suggested a kind of card the size of a credit card for a wallet pack but this would be an expensive option.

We discussed who they key players would be in getting information out to consumers. These included:

- Google who might be willing to provide information as part of their corporate social responsibility;
- Which?
- Money Saving Expert – although some doubted the usefulness of the information on their website.

It was noted that there are experts out there who able to advise on what words are 'trending' so that we can use the right words in our information.

It was also suggested that labelling of contact lens solution could be amended to include the code of practice logo. However, it was advised that the solutions market is decreasing (because of daily disposable lenses that don't require solution) and the chances of getting the manufacturers to change that packaging would be very slim.

[redacted] advised that we had now commissioned some consumer research into contact lenses. It was suggested that our contact lens research could ask people about what words they would use on a search engine when looking for information about buying/wearing contact lenses.

The following suggestions were also made about our consumer information:

- [redacted] could contact [redacted] who had done some work with Moorfields Eye Hospital;
- we could link in with EUROMCONTACT;
- we could link to the Health Standards Model – severity, susceptibility and benefits; and
- we could link to continuing education and training (CET) events e.g. at the BCLA Visionaries conference.

Action: [redacted] *to contact* [redacted]

6. Any other business

There was no other business and the meeting was closed at 12.30pm.

Stakeholder steering group on the voluntary code of practice for online contact lens supply / consumer awareness

Thursday 22 October, 2015, 2-4pm

GOC offices

Attendees (in person): [redacted]

Apologies: [redacted]

Minutes taken by: [redacted]

1. Welcome and apologies

[redacted] welcomed the meeting attendees. It was noted that we were due to have a new member of the group join us but that it was thought she could no longer attend.

2. Minutes of the last meeting

The minutes of the last meeting were agreed as accurate.

3. Feedback from the stakeholder working group

[redacted] updated the group since the last meeting. [redacted] advised that we had secured Council support for public consultation on the code of practice at its meeting on 29 July 2015. Throughout the consultation period (3 August to 12 October 2015) we had met with many of the professional bodies and that a key message that came up was to keep the activity around the code proportionate and simply.

The next stage for this piece of work will be how to monitor and manage the code, and how to educate the public about its existence.

A working group meeting was held on 17 September 2015. We had a new member of the group [redacted], who is an optical patient and it was really good to have [redacted] on board. The group looked at the following areas:

- how to monitor the code (outwith the GOC);
- progress on a code sponsor;
- work on consequence management;
- how to create a level of consumer awareness e.g. where the key touch points are when a patient is engaged (when the profession fits the contact lens; when a patient uses a consumer website or search engine to look for advice how to buy/wear contact lenses; when the patient looks on the contact lens suppliers' website); and
- further work on how to manage and validate the code.

[redacted] also explained he had been looking into the work of the 'nudge unit' around gaining maximum output from minimum input (both cost and effort). His thoughts around this are that we launch the code with a public relations (PR) campaign and then awareness of it will build organically and gather momentum over time.

[redacted] pointed out that engagement with the public is really hard and that we have to be realistic about this. We can use the HealthWatch website to promote the code.

[redacted] added that we need there to be a balance of stories, so that the message is positive rather than one of fear. [redacted] suggested that we might approach the manufacturers to see if they would be willing to promote the code of practice on contact lens packaging.

[redacted] said that eBay and Amazon had both worked with the Medicines and Healthcare products Regulatory Agency (MHRA) in the past so they might be interested in our work.

4. Report on consultation feedback on the code of practice

[redacted] presented the analysis document and outlined that there had been 74 responses to the consultation, which was positive when compared to some of our consultations (with the exception of our Standards consultation). The key points were that:

- the majority of respondents were supportive of the principle of a code of practice, in the absence of a change in the law, although many of these doubted the impact that it would have on protection of the public;
- some respondents were concerned that the code might lead to more patients buying contact lenses online because of the publicity linked to the code;
- there was also concern about how we would convince enough suppliers from outside of the UK to sign up to the code and how we would publicise it to patients;
- the vast majority of respondents felt that the code was clear in terms of what we would expect from suppliers who signed up to the code, and the clarity and accessibility of the code; and
- most respondents were supportive of the approach taken toward zero-powered contact lenses in the code (i.e. that those signing up to the code would not sell these), but some respondents were concerned that this would drive patients who wanted to buy these contact lenses to suppliers who would not provide appropriate advice.

It was noted that there are challenges to the code of practice but that it was felt that we are doing the right thing. We need to be careful that when the media pick up the code of practice that they don't just emphasise the negative messages. It was suggested that Kate Silverton at the BBC had been very good in the past.

[redacted] noted that there had only been one patient who had responded to the consultation and no other patient representative organisations. [redacted] wondered whether there was any requirement on us to consult further before ahead. [redacted] said that there was no requirement for us to do this but that our consumer research into contact lens wearers will help us in this area.

5. Initial insights from contact lens research

The initial findings from the focus groups were circulated to the group prior to the meeting. [redacted] summarised some of the key findings. Of particular note was awareness of and adherence to the British Contact Lens Association's (BCLA) advice. Some members of the steering group found it disappointing that some patients were either not listening to advice being given by the eye care practitioner or that it was not being given out.

[redacted] advised that we intend to use the report to help us with the consumer education messages and that we intend to publish the final report on our website to be made available to our stakeholders.

6. Amendments to the code of practice

[redacted] guided the group through the amendments and comments that she had made to the code of practice circulated before the meeting. These had been discussed with the working group that morning and [redacted] would update the steering group with the earlier discussions.

Comment 1: There was a suggestion that the code should require online suppliers to supply safe wear instructions with each and every interaction they have with the patient, including a 'no water' logo.

[redacted] advised that the stakeholder working group had felt that this suggestion was too detailed for the content of the code of practice and that it could be part of the more detailed guidance we would provide to the online supplier signing up to the code so that they know exactly what is expected of them. It was also noted that care was needed as to how to define 'each and every interaction with the patient'.

The stakeholder steering group agreed with the stakeholder working group.

Comment 2: The Optical Confederation comments that there is no clarification that the code applies only to soft contact lenses. Is this the case? I thought it was for all types of contact lenses, as surely all types can be bought online. Should the code apply only to soft contact lenses or remain as it is?

[redacted] advised that the stakeholder working group had felt that it is not clear why the code would only apply to soft contact lenses, even if these are the most likely to be sold online. It was agreed that the code apply to all types of lenses.

The stakeholder steering group agreed with the stakeholder working group.

Comment 3: Suggestion from the AIO to define what an online supplier is i.e. does it include a registered UK practice supplying only to their own patients?

[redacted] advised that the stakeholder working group had agreed that the code of practice should apply to any online supplier of contact lenses, even if it is a practice supplying only to their own patients (i.e. a closed website).

The stakeholder steering group agreed with this point, although many doubted whether an owner of a closed website would wish to do so.

Comment 4 (point 1 of the code): The Optical Confederation suggests that "The only advice given by a remote supplier should be to follow/seek the advice of the fitting ECP. Generic advice may contradict the advice given by the fitting ECP, leading to confusion." This seems to be at odds with the idea of producing guidance for the public on the safe use and wear of contact lenses. Is there a need to amend this sentence or leave it as it is?

[redacted] advised that the stakeholder working group had agreed that the code of practice should remain as it is, as one of the main purposes of the code is to ensure that patients are given advice about to wear contact lenses safely. The stakeholder working group felt that guidance that we produce for consumers can address the point regarding advice from an eye care practitioner i.e. one of the instructions will be that the advice from the patient's eye care practitioner is paramount, but we should also make them aware of the general advice to adhere to when wearing contact lenses.

The stakeholder steering group agreed with the approach of the stakeholder working group.

Comment 5 (point 4 of the code): There was a suggestion that we should include a tick box for customers to confirm that they have 'read and understood safe wear instructions'. Do we want to add this? Or should we say 'will comply with safe wear instructions provided by their eye care practitioner'?

[redacted] advised that the stakeholder working group felt that this was already included within the code within the bullet points under 4 and that there was no need to add anything further.

The stakeholder steering group wondered whether this was in fact something that should be included. It was suggested that we could mention that contact lenses are medical devices within this. It was agreed that [redacted] and [redacted] would consider how this point could be incorporated in the code and how it was different to the current point in the code which asks the customer to confirm that they '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'.

There was also a discussion about how point 4 of the code would work. Would there be a tick box for each of the sub-points on the supplier's website or would it simply be one tick box like there is for 'terms and conditions'. It was noted that there were positives and negatives for each option and that this needed to be considered further; we may wish to test this point with lay people.

Comment 6 (point 4f of the code): Should we amend this ('is ordering contact lenses prescribed by an eye care practitioner in the last two years') to one year? The consultation responses argued that contact lens specifications are usually valid for one year and so if you let patients order lenses prescribed two years ago and they are ordering a two year supply they could go up to four years without seeing an eye care practitioner. However, many patients do not have their specification and so on balance when we wrote the code we felt that two years was an appropriate figure since patients should have an eye examination at least every two years.

[redacted] advised that there had been a long discussion in the stakeholder working group about this point. There was discussion about the fact that some eye care practitioners will prescribe contact lenses for more than one year, and so one year was not thought to be appropriate when we originally drafted this point of the code. The original mentioned the expiry date of the contact lens specification but we could not refer to this given that a majority of patients are not thought to be in possession of their contact lens specification.

The stakeholder working group ultimately agreed that most patients tend to come back for a contact lens check-up after a year and so it was not clear why we were legislating for the few that were advised to come back in two years' time. It was agreed that two years was too prohibitive and that the people we are trying to protect are those who are buying online and existing from optometric care.

The stakeholder working group had agreed that we would consider how to re-word this sentence to make reference to one to two years depending on advice from the patient's eye care practitioner.

The stakeholder steering group agreed with the approach of the stakeholder working group.

Comment 7 (point 4g of the code): There is concern from some that the patient will be solely responsible for entering the correct details without verification from the supplier. I don't see how it is possible to amend this unless everyone had access to their specifications. Should we leave this sentence as it is?

The stakeholder working group agreed to leave the sentence as it is, given the reasons outlined above.

The stakeholder steering group agreed with the stakeholder working group.

Comment 8 (point 4h of the code): I have amended this ('is ordering a quantity of contact lenses that does not amount to more than two years supply') to one year. The Optical Confederation and others were concerned that if patients had seen an eye care practitioner in the last two years and were ordering a two year supply of lenses, that they could go up to four years without seeing an eye care practitioner. Do you agree with this amendment to one year?

[redacted] advised that the stakeholder working group had agreed to amend this sentence to one year given the discussions under comment 6 above.

The stakeholder steering group agreed with the approach of the stakeholder working group. [redacted] noted that the number of patients that order more than a one year supply of contact lenses was negligible.

Comment 9 (point 5 of the code): The Optical Confederation is concerned that the word 'requested' may allow patients to self-substitute. When drafting the code we did not feel we could refer to the contact lens specification here since most patients do not have this document. Instead, we came up with the assurance in point 4 of the code which asked the patient to confirm that they were only ordering lenses prescribed by an eye care practitioner. Do you agree that for now, given that patients do not always have access to their specification, we leave this sentence as it is?

[redacted] advised that the stakeholder working group had agreed to leave the term 'requested' as it is, given the reasons outlined.

The stakeholder steering group agreed with the stakeholder working group.

Comment 10 (point 5a of the code): The Optical Confederation advises that 'Manufacturers can recommend a new product without being aware of the patient's clinical status, which might render the new product unsuitable.' Are we still content that this sentence should remain as a suitable form of substitution?

[redacted] advised that the stakeholder working group were confident that the manufacturers had the expertise to determine when it was appropriate to issue a fit-match study. It was therefore agreed to leave the sentence in the code of practice as it is.

The stakeholder steering group agreed with this approach. It was noted that fit-match studies are not arbitrary and that perhaps the explanatory notes in the code could make reference to clinical studies.

Comment 11 (point 5b of the code): The Optical Confederation said 'We would welcome clarification on this point and in particular on the GOC's legal advice covering this point. Some private label lenses carry the original manufacturers name, making substitution a reasonable proposition (i.e. the only difference is the packaging). However, our understanding is that this is not always the case, and for

example the private label may list the optician as the manufacturer. We are not clear whether this would legally make the products different.' Are we still confident in these sentences?

[redacted] advised that the stakeholder working group felt that the concerns here were unfounded – we are concerned with identical products, regardless of name and who is listed as the manufacturer. It was agreed that we would add in reference to 'material, parameters and geometry' when referring to the product.

The stakeholder steering group agreed with the approach of the stakeholder working group.

Comment 12 (point 5d of the code): The Optical Confederation said 'We suggest that there should be a limit on the density of the tint as this could have safety implications, e.g. for driving.' Can you advise how we could limit the density of the tint in this sentence?

[redacted] advised that the stakeholder working group considered that concerns in this area are unfounded as there is a difference between spectacle tints and contact lens tints. It was suggested that the wording to this sentence could be improved.

The stakeholder steering group agreed with the approach of the stakeholder working group and suggested adding 'cosmetic' before the word 'tinted'.

Comment 13 (point 6 of the code): See point 5(a) above which may also impact on this sentence according to the Optical Confederation. Suggestion from a registrant that this sentence should be firmer as the manufacturer might not be aware of the patient's clinical status. Should we amend this sentence and if so, how?

[redacted] advised that the stakeholder working group felt that this point relates to comment 10 which the group felt was unfounded. It was therefore agreed to leave the sentence as it is.

The stakeholder steering group agreed with the stakeholder working group.

Comment 14 (point 7 of the code): There was concern from some respondents, including the AIO, that not allowing those signing up to the code to sell zero-powered contact lenses (ZPLs) might mean that patients will be driven toward less-reputable suppliers. We took this decision because ZPLs cannot be sold online under the current legislation as a registrant must be present and able to intervene in the sale. Are we still content with including ZPLs in the code?

[redacted] advised that the stakeholder working group noted that ZPLs are not currently a medical device and that this is where the difficulty lies. While one member of the group felt that online supplier should be able to sell ZPLs, it was ultimately agreed that this provision of the code needed to remain as to sell ZPLs (even if by a registrant) contravenes the law. The concerns from the AIO and others were

understood. It was felt that we can educate consumers about why they should not buy ZPLs online and it is then up to them to decide whether they wish to do so or not.

The stakeholder steering group agreed with the approach of the stakeholder working group.

The other amendments in track changes were agreed.

There was some discussion about whether 'eye care practitioner' should be amended to 'optician'.

7. Scope work for the stakeholder working group

[redacted] advised that there had been some comments raised during the consultation that the GOC wished to consider further. Although we will present the analysis of the consultation responses to Council in November, we do not proposed to take a final code of practice to Council until February. This should not delay implementation of the code, provided that a suitable sponsor comes forward.

[redacted] advised that the next steps for the working group were to:

- come up with a low cost model for the code sponsor and validation/monitoring of the code;
- engage signatories to the code;
- draft the consumer guidance on safe wear of contact lenses (making reference to the code of practice); and
- determine how to engage with consumers (and pursue suggestions such as Google).

It was suggested that it would be very helpful if the code could be endorsed by the optical professional bodies on their websites.

It was noted that publicity for the code could be a problem. We will need to think about how we publicise monitoring of the code, how many organisations to monitor each month and then how to follow-up any concerns. We may wish to publish the results of monitoring on the code sponsor's website (or even require a signatory to the code to publish it on their own website).

It was suggested that we could be doing more to publicise concerns around ZPLs.

It was noted that we will need some PR expertise for this campaign and the GOC is looking into this. We will need to ensure there are consistent media messages to manage expectations and consider joint press-releases with other agencies.

8. Any other business

There was no other business and the meeting was closed at 4pm.

Stakeholder working group on the voluntary code of practice for online contact lens supply / consumer awareness

Thursday 26 November, 2015, 2-4pm

GOC offices

Attendees: [redacted]

Apologies: [redacted]

Minutes taken by: [redacted]

1. Welcome and apologies

[redacted] welcomed the meeting attendees. Apologies were received from those members of the group listed above.

2. Minutes of the last meeting

The minutes of the last meeting were agreed as accurate.

3. Update from November Council

[redacted] advised that the consultation responses and an analysis document had been shared with Council at its November meeting. As the GOC was still considering the consultation responses, and wanted to take the findings of the contact lens research, it had been decided not to take a final version of the code of practice to Council in November. We will update Council at its next meeting in February.

4. Contact lens research

Having considered the contact lens research report, the following points were made:

- that the report was representative of the demographic in the UK;
- there was an over-representation of contact lens wearers in London, which was similar to some of the data collected by one of the manufacturers;
- the report suggests that compliance drops over time – there was a view that patients should be reminded of aftercare advice every time they attend for a contact lens check-up. We need to educate practitioners to do this;
- understanding people's behaviour doesn't mean that it can't be changed;
- some studies suggest that patients only take on 50-60% of what they are told in healthcare appointments, so how do we keep educating;
- it was surprising that a lot of customers use online as a top-up service (22%);

- it was fascinating that more people thought of contact lenses as a lifestyle product than they did a healthcare product – people need help to understand that contact lenses are medical devices;
- there are more mixed-channel wearers (i.e. those who buy both online and in-store) than we were aware of;
- it was surprising that the number of people with contact lens specifications was so high – but practitioners still need to educate patients about what a contact lens specification is;
- we know that retention rates in the first year of contact lens use are very low (about 50% drop-out rate after a contact lens fitting), although there are as many people trialling lenses for the first time as there are leaving; it is thought that only about 60% of patients continue to wear contact lenses after the first few years (due to discomfort, handling of lenses and/or price) – do the results of the contact lens research suggest that there is an increase in contact lens wearers beyond the one year mark, and if so, perhaps there is an increase in the number of spectacle prescriptions and contact lens specifications being given out? This could also be linked to the move toward dual appointments (i.e. sight test and contact lens fitting/check-up);
- it was noted that in 2005 the law changed but opticians weren't specifically advised that they needed to issue a contact lens specification, so not all registrants know that they need to do so;
- there was discussion about why so many people might be having contact lens check-ups more than once a year – this could be due to the fact that people wearing lenses for the first time would be having more than one contact lens check-up a year; also, people with complex needs would have more regular check-ups; there was also a suggestion that the use of locums leads to these practitioners recommending six-monthly rather than one-yearly check-ups because they are not seeing the patient regularly themselves;
- there was discussion about how to re-engage the profession and ensure that registrants are aware of the legal requirements around issuing contact lens specifications;
- it was noted that there was a misconception around the need to hold a sight test before a contact lens fitting; and
- there was a request for us to seek information from the Education Committee about how many people were undertaking contact lens training.

The working group was asked what harm might come to patients if they were not given their **contact lens specification**. The Stapleton and Dart papers suggested that people buying contact lenses online were more likely to have higher risk factors for microbial keratitits. However, it was thought that there was probably more research needed in this area. The challenge with not having a specification is that patients might not be wearing the lenses for which they have been fitted, essentially self-substituting. It was noted that there is no evidence around fit and material of lens other than the recent Wolffsohn research which found that lens of similar

parameters don't necessarily fit the same. However, the consequences of this are not clear and this is where more research is needed. There is no evidence that switching of lenses causes harm but there are higher risk factors with online purchase, which suggests that those who buy online might not be complying with aftercare advice. This leads to the need for more education for consumers. There was a suggestion that it is the lack of knowledge that causes harm, not necessarily the lens itself.

The research found that only 48% of people recalled receiving **aftercare advice** (advice and information about how to wear and look after their contact lenses) at their most recent contact lens check-up. It was thought that registrants might only give advice if the response to their list of standard questions (e.g. how long to you wear your contact lenses for? Do you wear your contact lenses in the shower?) was of concern.

It was noted that people don't always associate tap water with bath/shower water – they think they're somehow different. It was therefore suggested that any advice we give concentrates on '**no water**' rather than distinguishing between different types of water.

The group considered the findings in respect of compliance with the BCLA's categorisation of aftercare advice. It was queried whether there is any data on the level of risk associated with each category e.g. the lowest level of compliance is in relation to changing cases on a monthly basis, but how much does that matter? It was noted that the industry has helped by giving out a new lens cases with every bottle of solution.

It was suggested that we should be engaging with the contact lens solution manufacturers/suppliers e.g. pharmacies. It was thought that this advice around changing cases was in the instructions, but perhaps more could be done on the outside of the packaging to make it clearer.

It was considered that the role of the GOC is in advising its registrants for the benefit of their patients. The GOC should be doing more in this area to advise registrants about how to communicate with and educate their patients.

It was noted that all of the multiples are handing out leaflets on aftercare but we could be doing more to educate patients. The Health Beliefs Model may be relevant to us – it looks at issues such as susceptibility and severity.

It was noted that the issue with aftercare advice shows that the problem isn't just with online supply – it relates to all supply of contact lenses. The results of the contact lens research point to a need for a consumer awareness campaign and for registrants to better educate patients. We need to make it safer for people to wear contact lenses wherever they buy them from.

[redacted] 20/1/16 - agreed as accurate on 17/8/16

It was noted that there had been a study into patient anxiety in the consulting room. The conclusion was that patients generally only listen to the first and the last thing that they heard, and are often too busy listening out for information that they think they might be given rather than on what is actually being said. The problem is much wider than just optical patients; it relates to all healthcare appointments. There are studies out there that can help us with this.

It was noted that the BCLA advice separates out washing and drying hands, but that perhaps it could go further and say to 'thoroughly' dry hands. The water and tap water point was also mentioned again in relation to the BCLA advice.

5. Next steps re consumer awareness

[redacted] said that his understanding of the feeling from today's meeting was that consumer engagement should start with registrants educating patients about how to buy and wear contact lenses safely. In any event, the GOC does not have the budget to engage on a mass marketing campaign and so we need to be smart about how we promote our messages.

[redacted] advised that we a sub-group will be meeting in the next month to continue thinking about how to police a code of practice.

The research has brought up new issues that we need to consider further. We need to get some things right first (e.g. registrants issuing specifications, and patients being aware that they should receive a specification, as well as understanding the importance of regular check-ups). The code can then build on this more stable and compliant base.

There was discussion around how we could ensure that registrants understand their obligations in relation to contact lens fittings and how to better educate their patients. It was suggested that CET would be the best way to do this. It was also noted that contact lens opticians have to obtain at least 18 points related to contact lenses, whereas optometrists only need to obtain one point related to contact lenses.

It was felt that the optical print journals would be supportive in relation to educating about contact lenses and that a collaborative approach between registrants and patients should be recognised and shared.

6. Any other business

There was no other business and the meeting was closed at 4pm.

Stakeholder steering group on the voluntary code of practice for online contact lens supply / consumer awareness

Wednesday 13 January, 2016, 1.30-3.30pm

GOC offices

Attendees (in person): [redacted]
Attendee (by telephone): [redacted]
Apologies: [redacted]
Minutes taken by: [redacted]

1. Welcome and apologies

[redacted] welcomed the meeting attendees, including [redacted] who was attending the steering group for the first time. [redacted] introduced [redacted] as a patient who had experienced [redacted] approximately five years ago and has been working to raise awareness about contact lens safety ever since.

2. Minutes of the last meeting

The minutes of the last meeting were agreed as accurate.

3. Feedback from the stakeholder working group

[redacted] updated the group about the work of the stakeholder working group since the last meeting. He advised that the group had been aggregating its thinking around the three key touch points in a patient's contact lens journey – first contact lens fitting; internet search following fitting; and point of repeat purchase. The group had discussed the contact lens research but [redacted] decided not to share their thoughts at this stage until the steering group had had a chance to discuss it later on in the meeting.

[redacted] also explained that a sub-group of the working group had met to begin thinking about how we could validate and police a code of practice. The group had started by considering how the code could be implemented at no cost to the supplier or patient and had been looking at what might be possible.

4. Consultation responses

[redacted] outlined the presentation he was going to give which would cover five areas:

- recap on the illegal practice strategy;
- aims of the code of practice;
- feedback from the consultation;

- research findings; and
- options to consider.

[redacted] felt at this stage that he should declare an interest in talking about the consultation responses, declaring that he was representing a manufacturer. This was noted and it was mentioned that everyone in the room had introduced themselves at the beginning of the meeting, outlining who they work for, so any interests were clear. The GOC had convened the stakeholder groups to ensure that the sector was represented appropriately.

Recap on illegal practice strategy

[redacted] advised that the first strand of the strategy was to **continue to respond to complaints about illegal practice**. [redacted] said that the GOC had made changes to the way in which it will respond to complaints, via its prosecution protocol. It cannot prosecute all those are acting illegally but at the very least the GOC should be explaining the law. The GOC has some work to do in terms of putting the new process into action and is looking at putting more resource into its investigations team, so that that team can handle complaints about both fitness to practise and illegal practice. [redacted] said that the GOC needed to do better in this area and that several stakeholders in the room had made complaints about illegal practice that the GOC had not yet been able to address. There was a question about whether patients who complained were updated about the outcome of the complaint. [redacted] thought that this was the case but said that he would look into this and confirm.

Action: [redacted] to look into whether patients who complain are kept informed about the outcome of the complaint.

The second strand of the strategy was **collaboration with other enforcement bodies**, for example, Trading Standards. The GOC issued a joint press release with Trading Standards around Halloween and there was media interest as a result. There are a number of pharmacies who still appear to be selling zero powered contact lenses. This should not be happening and the GOC should be able to do more around this by working with the General Pharmaceutical Council. The GOC also needs to develop further its links with the Medicines and Healthcare products Regulatory Agency (MHRA). The GOC is also considering how it might be able to work with the Advertising Standards Authority (ASA) to deal with misleading claims on websites.

The third and fourth workstreams (**guidance for patients on contact lenses** and **development of voluntary code of practice on online contact lens supply**) are areas that the stakeholder steering and working groups are focusing on.

[redacted] said that the GOC had taken a big step forward in relation to the fifth workstream (**research and intelligence-gathering**) with the contact lens research study to understand behaviour and where people are buying contact lenses from. It would

also give a benchmark on which to assess the success of any code of practice. [redacted] noted that we would be discussing this report later on in the meeting.

Aims of the code of practice

[redacted] reminded the group that the intention behind the code of practice had been to address the risks to the public identified by the Europe Economics research by improving the practice of online suppliers, with a recognition that the online market was likely to continue to grow.

The code was designed to incentivise suppliers to provide better information and advice and encourage customers to have regular aftercare appointments and eye examinations.

The draft code takes into account the legal framework and current business practices, being mindful of the legal framework but trying to avoid being constrained by it. The processes around contact lens supply are not particularly helpful as although there is a requirement for suppliers to verify a specification with the registrant, there is no reciprocal obligation on the registrant to verify it. When the legislation was originally drafted, internet sales of contact lenses did not exist. So the GOC was trying to be creative in improving public protection as changing the law would be a long and involved process.

It was suggested that the GOC's new standards (standard 10 in relation to working collaboratively with colleagues in the interests of the patient) obliged registrants to work with those suppliers trying to verify a specification. [redacted] said that this might be an area where the GOC could produce guidance for registrants about what this standard means.

Feedback from the consultation

[redacted] made the following points which summarised the feedback from the consultation exercise:

- the majority of respondents were supportive, although many doubted the impact on public protection i.e. the support was qualified;
- respondents generally thought the code of practice was the right course of action in the absence of being able to change the law;
- there was concern about how we would publicise the code so that patients were aware of it;
- there was concern about how we would convince suppliers from outside UK to sign up i.e. what was in it for the supplier? The answer being the logo;

- the need for the code of practice to be launched in parallel with a campaign to educate patients about how to buy and wear contact lenses safely i.e. the code in itself would not be sufficient;
- there was concern that the code might breach competition law if it has a detrimental impact on businesses operating within the law; and
- there was a challenge as to whether there is enough evidence to support what the code says about "substitution".

[redacted] advised that the GOC had been considering the last two points in particular. He said that as a public body the GOC is subject to judicial review of its decisions and that organisations that signed up to the code could potentially be subject to legal challenge as the code could constitute an agreement between undertakings for the purposes of competition law.

In relation to substitution, the code went beyond the law on the basis of the Europe Economics research finding that there is an increased risk for those wearing contact lenses if they are not following the advice of a professional and not going for regular check-ups, and that this risk increases when buying online. However, we needed to consider whether the evidence of potential harm was enough to justify the way in which the code currently dealt with substitution. Companies that have been practising substitution might have been doing so for a long time, having taken the view that it is legal for them to be doing so. We would need to be able to show that the code was proportionate and as substitution is not illegal we would need to have a strong evidence base as to why we should include something that goes beyond the law.

There was a strong feeling that substitution of contact lenses, apart from in the circumstances set out in the draft code, was not in the interests of the patient and could put them at risk, even if it was not technically an illegal practice to engage in. The following points were raised:

- concern that patients were not aware that they were being provided with an alternative product to that which they had been prescribed;
- concern that some websites were substituting daily disposable lenses for three monthly contact lenses and that patients could use these in the same way that their eye care practitioner had prescribed (e.g. sleeping in lenses that should not be worn overnight);
- substituting contact lenses could undermine the fitting process envisaged by the legislation; and
- manufacturers have to be extremely careful about any claims they make, including recommending a particular lens as a replacement for a different lens and commission expert studies to show that lenses have similar parameters.

It was thought that manufacturers/suppliers that substitute lenses should have data for every single lens they substitute to back up their claim that the lens can be appropriately switched.

There was discussion about further work that could be done to gather evidence around the practice of substitution. Various views and ideas were put forward and these were not necessarily shared by all members of the group:

- the idea that it could take years to carry out the appropriate research to look into concerns around substitution , so it is not likely to be worth investing in at this stage;
- a suggestion to survey a patient group of 500 patients across the world that had experienced acanthamoeba keratitis to see if there were any possible links to substitution;
- a suggestion to look for evidence not only of serious eye conditions such as keratitis but also substitution that results in eyes becoming red or itchy;
- considering the law around medical devices and in the light of this, whether it was appropriate to substitute contact lenses;
- considering this from a consumer protection angle – whether patients are being misled in that they think they are receiving products that are the same as that which they have been prescribed;
- eye care practitioners should be educating patients about the reason and purpose of the particular type of lens that they have been fitted for and why it is important that they do not substitute the lens;
- contacting Trading Standards and the ASA to address claims made about substitution of lenses;
- seeking advice from the Competition and Markets Authority (CMA) and/or the MHRA regarding the medical devices angle;
- concerns around substitution were not just around a company recommending an alternative lens, but around a patient selecting an alternative lens that they have not been prescribed because they do not have to provide their specification to the website;
- a suggestion to include the modality of the contact lens as part of the code of practice and to define the meaning of 'replication' within the legislation (AB advised that we would only be able to include provisions within the code that went beyond the legislation if there was evidence to justify its inclusion); and

- a suggestion that the GOC could give further advice to registrants about what a specification should contain e.g. why the particular lenses have been chosen.

There were concerns around the requirement to verify a specification within the legislation, as there does not seem to be any reason to require a supplier to verify a specification if they already have a copy of it.

It was suggested that we re-focus the code to concentrate on aftercare advice and ensure it was in line with the current legal framework. This would not preclude the other ideas that have already been mentioned to try to address concerns around substitution.

There was discussion around the value of a code of practice without substitution. It was felt that it is still important to educate patients about the importance of aftercare. The code is one part of the illegal practice strategy and, in any event, it was felt to be appropriate to press forward with the consumer awareness workstream to educate patients.

It was suggested that eye care practitioners need to think about how to position and frame how they give out documents such as spectacles prescriptions and contact lens specifications, in order to educate patients.

5. Contact lens research

Members of the group had been provided with a draft copy of the contact lens research, as part of the papers for the meeting. [redacted] drew attention to the following findings in particular:

- 59% have **contact lens specification** from most recent check-up – the group was surprised by these results as originally we thought that this figure was much lower. The code was drafted on the basis that a very small percentage of people would have their specification. Should we therefore have a re-think about how we drafted the code?
- 48% were provided with **aftercare advice**; 35% said they were not; 17% could not recall – it was felt that both the eye care practitioner and the patient were potentially to blame in this scenario. There is a lot of research out there to suggest that patients get too many messages at healthcare appointments. This prompted a discussion around what this means for the sector. It was noted that some people only get advice once (e.g. when they are fitted for contact lenses for the first time). Those who have been wearing lenses for longer are less likely to be receiving aftercare advice.

It was felt that aftercare advice was a significant challenge for the sector and that eye care practitioners needed to receive advice on how to deliver education messages to patients. It might be the case that some patients think they have not

received aftercare advice because of the way that they have been communicated with. It was felt that the GOC could do more in this area for registrants, perhaps in relation to compulsory CET (contact lenses and communication). The BCLA could also help with this.

It was noted that there is a difficulty as a lot of research suggests that patients do not retain all of the information they are given at healthcare appointments. The messages need reinforcing to patients and we need to focus on five key messages. It was suggested that this could be done by the optical equivalent of MacMillan Nurses e.g. optical assistants. We would need to make sure that these people are appropriately supervised and trained if their role is to widen to give contact lens advice. The new standards emphasise the importance of supervision.

There have been several campaigns that have resulted in behavioural change that we could learn from e.g. drink-driving and wearing seat-belts. We can also learn from models such as the Health Beliefs Model and work done by Bausch & Lomb on 'Powers of persuasion'. We can tackle this with commitment and explaining to patients the consequences of not following advice.

6. Options for the way forward

[redacted] presented the following options for the way forward:

a. Press ahead with launching patient guidance;

b. Revise the code so that it is more closely aligned with the current legal framework:

   i. for online suppliers;

   ii. for all suppliers – originally the issue was focused on online suppliers but the research suggests that aftercare advice is an issue for all suppliers of contact lenses;

c. Develop guidance to promote awareness of current legal obligations;

d. Build on work to develop the code by developing proposals for legislative change – however, this would be a long term process that would require evidence of patient harm; and

e. Consider value of further research and if so, how this might be carried out.

[redacted] noted that the group appeared to be keen to maintain momentum, particularly in the following areas:

- guidance for patients on how to buy and wear contact lenses safely;
- supportive material for registrants to help patients understand the aftercare messages they are given, either through guidance and/or CET modules.

It was noted that a patient base is very powerful and we should get patients' input and help with our proposals.

It was queried whether it would be possible for the GOC to clarify the meaning of replication, perhaps through amending its rules. [redacted] said that he did not think that this was within the GOC's powers but that he would look into it.

It was suggested that the contact lens research report could be peer-reviewed and published in a journal.

It was agreed that the GOC would consider all of the suggestions made at the meeting and develop a proposed way forward, which they would share with the group before reporting back to Council.

7. Any other business

There was no other business and the meeting was closed at 3.40pm.