

Annex 4: Note of Standards Committee discussion on adjustable focus spectacles

Meeting held on 8 October 2015

The Standards Committee had been provided with a cover paper enclosing the Adlens' regulatory white paper and Professor William Neil Charman's independent report. They were asked to provide us with their views on the over the counter sale of adjustable focus spectacles without a prescription, including their views on:

- any benefits which these products might bring; and
- any adverse effects that these products might have on the public's health and safety.

During discussion, Committee members raised the following views:

1. Concern that the sale of these products would distract the public from regular eye examinations, particularly at a time when the sector is trying to raise the profile of eye health and encourage earlier detection of eye health problems. There was particular concern about this creating a new generational issue i.e. young people (aged 16 upwards) who are in need of glasses and who might not get their eyes tested if this product were made available to them without a prescription. Were teenagers and young adults able to self-correct their vision this might instil a belief that because they can "see" by using variable focus lenses there would be no need to have regular eye examinations.
2. The Committee lacked assurance from either of the reports presented that the product is safe. The reports did not provide assurances about whether the spectacles would meet specific legal standards, such as Driver and Vehicle Licensing Authority (DVLA) standards for driving, including drivers of public service vehicles, and standards for pilots. There was also concern raised about whether the product met the relevant standards in terms of providing a sufficient "field of vision" both horizontally and vertically, as required by the DVLA for driving.
3. Committee members raised the concern that there was no mention in the Adlens White Paper about whether the spectacles would be safe for those with impairment to binocular vision (i.e. a lack of ability to maintain a stable single image of an object with both eyes) and also that these spectacles could create a binocular vision problem making the vision variable and unstable, with the potential for intermittent periods of double vision.
4. Sale of this product was likened to previous discussions around prescription swimming goggles – it had been decided not to allow sale of these over the counter as the concern was that people would inappropriately use these for driving, which would endanger the public.

5. The power range of Adlens' adjustable focus spectacles was thought to be too great and if the product were restricted to 0 to +4 D (as "ready readers" currently are) the view of the Committee was that this might be acceptable, as it would reflect the parameters of the current legislation.
6. Selling adjustable focus spectacles over the counter without a prescription could also have consequences for selling ready made spectacles with any power of lenses. .
7. The arguments in the Adlens paper in favour of over the counter sale of adjustable focus spectacles in the UK were generally considered to be weak although the market for this product was not thought to be significant, the view being that most people in the UK have good access to sight tests, eye examinations, affordable spectacles and other optical appliances.
8. There was concern that Professor Charman's report understated the medical risk of adjustable focus lenses to people with hyperopia (i.e. farsightedness where distant objects may be seen more clearly than objects that are near) and in particular older people with hyperopia – the concern being that these people are at higher risk of angle closure glaucoma and it is therefore vital that they have regular eye examinations.
9. It was noted that these products were originally developed for use in the developing world – it was felt that a solution for a developing world problem was not transferable for the UK. It was not clear what benefit the product would bring and there were no significant barriers to accessing appliances which correct refractive error specific to a patient's needs.
10. Concern that adjustable focus spectacles were made from a polycarbonate material, which has a low V-Value and therefore will suffer from transverse chromatic aberration leading to poorer off-axis vision.
11. Concern that the Adlens report was misleading in some areas e.g. in the section on vision for safer roads and the comments regarding best sphere correction (which includes an 'assessment' and incorporation of astigmatism correction). The fact that a patient with astigmatic components in their refractive error (even up to 1.50-2.00DC), corrected by the variable focus lenses, might feel that their vision is 'satisfactory' is of concern as it could be argued that it is not possible for a patient to safely and appropriately gauge what level of visual acuity fulfils legal requirements for driving.
12. The Committee raised the fact that it has been documented in the academic literature that 'self-adjustment' by patients is very subjective and not always accurate, and there was concern that the public would be put at risk by people driving in these spectacles.
13. Various comments were expressed about whether the adjustable focus spectacles would be a suitable interim measure for patients who had recently had cataract surgery and were awaiting their post-operative refraction. There was a concern that these spectacles could encourage a post-cataract patient

to self-correct and not check with their optometrist whether they are within the legal limits for driving.

Overall, there was a concern among Committee members that the sale of adjustable focus spectacles 'over the counter' may lead to increasing numbers of people feeling that it was not important to have their eyes checked which would in turn impact on public health and safety, patient safety and eye health. The concern for public safety centred around drivers of private vehicles and public service vehicles who might incorrectly self-adjust and therefore cause a danger to the public.