Response to MHRA Consultation on the Revision of European Legislation on Medical Devices

Thank you for inviting our comments on this consultation. The Optical Confederation represents the 12,000 optometrists, the 6,000 dispensing opticians and 7,000 optical businesses in the UK who provide high quality and accessible eye care services to the whole population. The Confederation is a coalition of the five optical representative bodies: the Association of British Dispensing Opticians (ABDO); the Association of Contact Lens Manufacturers (ACLM); the Association of Optometrists (AOP); the Federation of Manufacturing Opticians (FMO) and the Federation of Opticians (FODO). As a Confederation, we work with others to improve eye health for the public good.

The Optical Confederation's membership also includes optometrists, contact lens opticians and registered clinicians regulated by the General Optical Council (GOC) who are entitled to fit contact lenses under the Opticians Act. This role includes assessing patients' suitability for wearing contact lenses (CLs), fitting CLs, providing advice on lens hygiene and maintenance, and aftercare.

Introduction

Overall we welcome the proposed new features and agree that they will provide greater transparency, improve traceability, deliver greater proportionality for higher risk appliances and improve reporting channels. We believe that these changes will provide greater protection for patients and the public. As the representative bodies for community optical professionals, our chief interest lies in the proposed inclusion of non-corrective contact lenses in the definition of 'medical device' under European law which we very much welcome.

Non-corrective contact lenses are often used in practice for clinical and cosmetic reasons. Clinical reasons include their use to camouflage a damaged cornea, to therapeutically block light to alleviate photophobia for example in albinism or congenital anomalies or trauma to the iris. Cosmetic reasons include changing the colour of the iris and sometimes for social or fun purposes. Whatever their use, these contact lenses have a similar impact to powered lenses on the oxygenation and therefore the metabolism of the cornea. They must be appropriately prepared and their materials must allow for adequate oxygen transfer to the cornea. Moreover, any pigments used for colouring a contact lens must be non-toxic to the ocular surface, stable and all contact lenses must be stored in sterile packaging to avoid contamination.

In this respect, whatever its intended use, a contact lens is a contact lens and its misuse can result in serious ocular complications (such as ulceration or infections) potentially leading to loss of the eye. In order to protect the public, all contact lenses

should be subject to the same harmonised standards and post-marketing vigilance systems. Research has indicated the same risk profile between non-corrective and corrective lenses and there is arguably a higher risk with non-corrective lenses due to the fact that wearers will often be inexperienced at handling them, cleaning after use and maintaining their sterility.[1,2]

Since 2005, the USA has classified non-corrective contact lenses as medical devices to protect public eye health. In recent years, Japan (2008), Canada (2012) and China (2012), have also done so. Under the UK law governing the distribution of contact lenses, both corrective and non-corrective contact lenses should be fitted and supplied following a regulated professional's assessment of the patient's suitability.[3]

To date, under EU legislation, non corrective lenses have been outside the provisions of the Medical Devices Directive, and as outlined in the consultation, they are proposed to be included. We very much welcome this and MHRA's support on grounds of public protection as it corrects a long standing anomaly in the supply chain for non-corrective cosmetic contact lenses under European law which puts individuals, and particularly young people, at risk. [4]

When supplied appropriately (with advice on fitting and cleaning), contact lenses are very safe to use. Research has indicated that where lenses are supplied through unconventional channels (through which non-corrective lenses are often supplied) without adequate fitting/ selection, handling or care instructions, patients are at an increased risk of infections which often require medical interventions. [1, 2, 5]

We are confident that the provisions to include plano cosmetic contact lenses in the MDD will not place any additional burden on the eye care industry or healthcare systems. By contrast, harmonisation of the provisions governing supply simplifies and streamlines the burden on industry. Regulating all contact lenses similarly will better protect patients and should ensure that fewer present to healthcare professionals with contact lens related complications due to inappropriate materials or use.

We have replied to questions below which relate to eye care and our position as set out above.

[1] Steinmann TL et al (2003) Ocular complications associated with the use of cosmetic lenses from unlicensed vendors, *Eye & Contact Lens* 29 (4) p.196-200

[2] ECLF (2011) The European Contact Lens Forum – The results of the CLEER- Project, *Contact Lens and Anterior Eye* 34 p. 293-296

[3] Opticians Act 1989 as amended in 2005

[4] Cunlin Wang et al (2010) Emergency Department Visits for Medical Device-Associated Adverse Events Among Children, *Paediatrics* 126 p. 247-259

[5] Fiona Stapleton et al (2008) The incidence of contact lens-related microbial keratitis of varying severity in Australia, *Ophthalmology* 115(10) p. 1665-62

Chapter I: Scope and Definitions

Question 1:

As above, we agree with MHRA that the proposed changes to the scope of the medical devices regulations are helpful and welcome the clarification as to which devices are included. Further we agree that these changes will not have a significant impact on UK based manufacturers.

Q. 2:

Not applicable to our response.

Q. 3:

We strongly agree with the extension of the definition of a medical device to include implantable or invasive products without a medical purpose. For non-corrective contact lenses, this move brings European legislation in line with other jurisdictions and the UK's laws governing their distribution. We feel that the public health grounds for doing so are robust and we are pleased to see that MHRA shares this view.

Q. 4-8:

Not applicable to our response.

Q. 9:

Provided that there are adequate checks and balances in place, including requirements to conduct a cost-benefit analysis and consult with stakeholders where appropriate, we agree with MHRA that delegating this power to the Commission would be a helpful way to provide legal certainty and consistency across the Single Market.

Chapter II: Making available of devices, obligations of economic operators, reprocessing, CE marking, free movement

Q. 10:
We agree with the MHRA's analysis and welcome the consistency through reinforcing the obligation on manufacturers to provide a clinical evaluation when demonstrating the conformity of their devices with the safety and performance requirements in the Directive.

Q. 11:

Not applicable to our response.

Q. 12:

We agree that a device or service involving a device for diagnostic or therapeutic purpose sold over the internet must comply with both of the proposed regulations. We would add that internet supply direct to patients should also conform to laws governing the distribution of contact lenses in Member States (such as the Opticians Act in the UK). We would welcome further clarification as to how this would be enforced and the means of redress open to national competent authorities.

Q. 13:

We agree with the MHRA that Member States should in limited circumstances have the opportunity to object to a harmonised standard (i.e. where it may not meet the essential standards). We would caution that these circumstances should be limited and only used for challenge and improvement of the harmonised standards.

Q. 14:

Not applicable to our response

Q. 15:

Not applicable to our response.

Q. 16:

We support the principle that manufacturers and authorised representatives should identify a person responsible for regulatory compliance. Further, we agree with the MHRA that there should not be duplication of tasks and that the framework should be proportionate for SME manufacturers of low risk devices.

We would however like to add that internet supply direct to patients is the same as distribution and the obligations on 'distributors' should also apply to internet supply direct to patients.

Q. 17:

Our members already meet the general obligations governing supply and distribution of medical devices and we do not foresee any significant additional costs for our members from the obligations outlined here.

Q. 18-21:

Not applicable to our response.

Q. 22:
We agree with the MHRA that UK manufacturers and distributors already comply with these provisions (e.g. Declarations of Conformity) and foresee no significant impact.

We would like to add that the current RG2 framework can be confusing. As stakeholders we would welcome being included in any revision of the RG2 forms and associated MHRA guidance to ensure they are as clear as possible for users.

Q. 23-24:

Not applicable to our response

Chapter III: Identification and Traceability of Devices

Q. 25:

We agree with the MHRA that the proposed simplification of measures designed to trace medical devices along the supply chain is welcome.

Q. 26:

With the advent of technology in the supply chain and other requirements to keep patient records, we do not feel that this would place an additional burden on economic operators. In the interests of a level playing field, we would however wish to have clarity that internet suppliers are subject to the same requirements to ensure that medical devices supplied via the internet are similarly traceable.

Q. 27:

We agree in principle that a system of unique device identification would be beneficial. However we have some concerns about the practicalities of implementing this; please see our response to question 28.

Q. 28

We have considerable concerns about the practicalities of implementing the proposed system of unique device identification. Taking the example of an individual pair of contact lenses, we believe that the additional costs relating to the modification of packaging would be prohibitive and impractical.

We suggest that it should be sufficient to identify a box of contact lenses (all the same parameter and lot number) rather than having to identify up to 180 contact lenses (in the same box) individually. Therefore, we suggest unique device identification is restricted to the carton packaging and not required for individual contact lenses.

Q. 29-68:

Not applicable to our response

Submitted by Ben Cook on behalf of the Optical Confederation
21st January 2013