Optical Confederation submission to the Health and Social Care Committee
inquiry into the impact of a no-deal Brexit on health and social care

1. The Optical Confederation represents the 13,000 optometrists, 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).

2. The Optical Confederation represents eye health professionals and providers (individual practitioners and companies) who operate in both the NHS and the private sector, and also the manufacturers of medical devices (spectacle frames, spectacle lenses, contact lenses and solutions, and ophthalmic equipment).

What is the impact of a no deal Brexit likely to be on the optical sector?

3. In practising their professions of assessing and correcting vision and of investigating and treating eye health conditions, optometrists and dispensing opticians routinely prescribe, use or supply various medicines and medical devices (including spectacle frames, spectacle lenses, contact lenses and solutions, and ophthalmic equipment) to their patients.

4. A not insignificant number of optical businesses also manufacture spectacle frames, spectacle lenses and contact lenses and solutions in the UK. These products are sold across Europe (and world-wide) as well as the UK.

5. A no-deal Brexit could therefore have a variety of negative impacts on our industry specifically in relation to:

- The regulation and licensing medicines and medical devices
- Tariffs on imports and exports, which would impact on both British businesses and patients
- Ongoing ability to access medicines and medical devices, particularly new and innovative products which would benefit patients but may take longer to reach the UK market.
- Ensuring patient safety.

Each of these issues would have significant implications for optical practices (providing a healthcare service and running a viable business), UK manufacturers and patients.

Licensing

6. Medicines and medical devices used and prescribed to people with eye health and vision conditions are subject to international and EU licensing, standards and regulation. Although the ISO system is outside EU jurisdiction, the UK works with colleagues across Europe on both ISO and CEN committees to agree and set standards that apply internationally. In general, CEN, the European Standards body, has adopted the ISO standards unchanged in the ophthalmic optical field. The MHRA, which has responsibility for the regulation of medicines and medical devices in the UK, has played an important role in negotiating standards across Europe for the benefit of both EU and UK citizens.

7. With the introduction of the Medical Devices Regulation, work is underway to enable full implementation (including, for example, the introduction of Unique Device Identifiers which will need to be registered on the Eudamed database). Revisions of various ISO/CEN standards are underway and to make some revision of current standards. Implementation of this Regulation will impact on UK healthcare providers. However, with a no deal Brexit it is not clear how the UK would be able to contribute to and influence discussions and decisions on standards, for example through participation in working groups.

8. Thereafter, it will be important to ensure on an ongoing basis that the legal and regulatory system post-Brexit continues to recognise products that are licensed across the EU and that approaches to licensing and standards remain consistent and that common standards continue to apply across Europe. Without such agreement, the UK will not be able to benefit from new products that are licensed in the EU. And UK manufacturers will not be able to access EU (and potentially other) markets.

9. It seems unlikely that the UK market would be sufficiently large for manufacturers to seek separate licenses for the UK market, if these differed from the current CEN standards.

What are the risks to patients and the healthcare system of leaving without a withdrawal agreement?

10. Medicines and medical devices are licensed for sale across Europe. If there is no agreement on licensing of medicines and medical devices, and new tariffs are imposed on goods imported to the UK, it will impact on the ability of eye care practitioners to continue to access the medicines and devices that patients need. We are concerned that without a deal any of the following scenarios may become reality:

- Access to medicines and medical devices becomes limited as the number of companies marketing to the UK reduces,
- The costs increase, as a result of new tariffs
- Safety is compromised, as the UK no longer has access to the most up to date medicines and devices, and potentially opens the market to lower quality products from other suppliers.

11. In short, without a clear commitment to maintaining European standards in medicines and medical devices there is likely to be a poorer service for patients and less

choice and potentially a risk to patient safety, if the market opens up to products with different (lower) standards.

12. It is also essential to maintaining low UK and NHS health care costs that healthcare providers do not have to navigate new or multiple standards, or increased tariffs on goods manufactured elsewhere in Europe.

Optical Confederation
15 October 2018