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EUROMCONTACT KEY POINTS ON MEDICAL DEVICES REGULATION

EUROMCONTACT is the European Association representing the contact lens and lens care products industry in Europe. Euromcontact represents more than 90% of the European contact lens market.

EUROMCONTACT supports the revision of the Medical Devices Directive to guarantee the highest level of consumers' safety as well as innovation in a very competitive industry segment.

EUROMCONTACT would like to highlight some key points for the contact lens industry:

- **Highest level of safety for consumers is the ultimate goal. The industry therefore supports the Commission proposal to include non-corrective contact lenses in Annex XV and calls upon Member States and European Parliament to support the Commission Proposal.**

- Some of these devices are used for medical purposes (UV blocking contact lenses that help protect against transmission of harmful UV and into the eye so as to alleviate photophobia as seen in albinism; bandage lens for corneal protection or for post-surgical conditions; etc) and are CE marked as medical devices as they fulfill a medical purpose;
- Colored corrective contact lenses are today available on the EU market;
- These devices have the same technical characteristics and are used in the same way as a corrective contact lens bearing a CE mark;
- These devices have the same risk profile therefor the same level of safety should apply;
- There is an extensive list of ISO standards that apply to contact lenses (see Annex A). These standards are used to demonstrate conformity to the Essential Requirements in order to CE mark the product. These standards do not differentiate between corrective and non-corrective lenses, and can be applied to both types of lenses. Euromcontact therefore believes that requirements regarding technical specifications, clinical evaluation and biocompatibility are appropriately addressed.
- Today, plano lenses are regulated as medical devices in all industrialized countries except in the European Union.

Today, aesthetic contact lenses without a medical purpose fall under the General Product Safety Directive, which, unlike the MDD, does not provide detailed and appropriate essential requirements, like the sterility requirements or the vigilance.

Legal predictability and certainty is crucial for the industry. A limited and positive list of devices falling under the scope of the legislation, with clear criteria to allow for regular updates, provides such certainty. A specific legislation on aesthetic devices may lead to two different sets of rules, for devices presenting the same risk-profile.

- **The industry supports the definition of 'duration of use' indicated in Annex VII 1 [Classification Criteria] as proposed by the Commission. In case where the definition would not take into account intermittent use, this would automatically lead to the up-classification of some contact lenses without any benefit to**

consumers' safety. It may also lead to the up-classification of a wide range of other devices, like surgical instruments.

- Risks related to the long term effect or the accumulated use of devices and its effect on patients would be better covered by adding specific and appropriate Essential Requirements (clinical evaluation, risk assessment) rather than by an up-classification, which is not likely to address those particular points;
- Available vigilance data have not indicated an increased risk related to the long term and intermittent use of contact lenses that might justify an up-classification.

Commission proposal on Duration of Use:
1.1. 'Transient' means normally intended for continuous use for less than 60 minutes.
1.2. 'Short term' means normally intended for continuous use for between 60 minutes and 30 days.
1.3. 'Long term' means normally intended for continuous use for more than 30 days.

- **Scrutiny procedure (Art. 44) should not prevent innovation:**

- In case a scrutiny procedure would be adopted for high risk or novel medical devices, it should not prevent innovation and innovators should not be penalized. Therefore there is a strong need to ensure a fair level playing field and fair competition, avoiding that the first innovator would take the burden and been penalized;
- A clear set of rules should therefore apply to all manufacturers of high risk devices when putting new devices on the market;

- **Single use versus reusable:**

Euromcontact supports the Commission proposal regarding the reuse of single use devices. Euromcontact is supportive of a strong European regulation at European level on the reprocessing of single-use devices. The EU Parliament proposal, foreseeing that all devices would be reusable, unless the manufacturer has demonstrated the contrary, would lead to an unnecessary burden for manufacturers. The articles in the regulation dealing with reprocessing are aimed at medical devices used in a hospital setting. However, by including all medical devices in the scope of these articles, manufacturers of devices for consumer use, like contact lenses and lens care products, have to provide the same level of evidence for devices that are highly unlikely to be reprocessed. Euromcontact therefore proposes to exclude devices for consumer use from the scope of the articles dealing with reprocessing.

- **Additional labeling requirement:**

Euromcontact is very concerned about the requirement to add the text 'medical device' next to the CE mark (EP amendment 136, supported by the EU Commission). The current labeling requirements are already challenging due to the limited space on the contact lenses packaging. Having to add an additional text to the CE mark seems difficult due to space limitations and even impossible if a translation in all official languages would be required. It also raises questions regarding the compliance with eventual other applicable Directives or Regulations, as the CE mark usually indicates compliance with all applicable legislation, therefore the CE medical device may be misleading. Euromcontact strongly suggests deleting this new requirement as it will not enhance patient safety but will put a heavy burden on manufacturers.

- **Hazardous substances:**

Euromcontact is very concerned about the fact that the EU Commission is open to expand the scope of the hazardous substances to all CMR substances (EU Commission position on European Parliament amendments). This would include substances like Boric Acid, which is commonly used in contact lens care solutions and contact lens storage solutions. Replacement of the substance would require extensive testing or even complete reformulation of the product. Especially for SMEs, this may be too costly in order to maintain the product on the market. Euromcontact strongly suggests limiting the requirements for hazardous substances to identifying the substance on the label to minimize the impact on SMEs and product availability on the market.

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EUROMCONTACT is the voice of European contact lens and lens care industry to the European Institutions, media, stakeholders and the public. EUROMCONTACT is the European Federation of National Associations and International Companies of Contact Lens and Lens Care Manufacturers. EUROMCONTACT members include National Associations of Manufacturers, representing Netherlands, France, Germany, Italy, Spain, Switzerland and the United Kingdom; the global companies Alcon, AMO Ltd., Bausch & Lomb, CooperVision, Johnson & Johnson Vision Care, Menicon; and the European Federation for the Contact Lens Industry EFCLIN.

Annex

Clinical testing:
EN ISO 11980:2012 - Ophthalmic optics - Contact lenses and contact lens care products - Guidance for clinical investigations

Biocompatibility testing:
EN ISO 9394:2012 - Ophthalmic Optics - Contact lenses and contact lens care products - Determination of biocompatibility by ocular study with rabbit eyes

Fundamental requirements:
EN ISO 14534:2011 - Ophthalmic optics - Contact lenses and contact lens care products - Fundamental requirements

Labelling:
EN ISO 11978:2000 - Ophthalmic optics - Contact lenses and contact lens care products - Information supplied by the manufacturer

Stability testing:
EN ISO 11987:2012 - Ophthalmic optics - Contact lenses - Determination of shelf-life

General requirements:
EN ISO 18369-1:2006/Amd. 1:2009 - Ophthalmic optics - Contact lenses - Part 1: Vocabulary, classification system and recommendations for labelling specifications
EN ISO 18369-2:2012 - Ophthalmic optics - Contact lenses - Part 2: Tolerances

Finished lens parameters:
EN ISO 18369-3:2006 - Ophthalmic optics - contact lenses - Part 3: Measurement methods

Physico-chemical properties / Lens extractability and leachability testing:
EN ISO 18369-4:2006 - Ophthalmic optics - Contact lenses - Part 4: Physicochemical properties of contact lens materials

Preservative uptake and release testing:
EN ISO 11986:2010 - Ophthalmic optics - Contact lenses and contact lens care products - Determination of preservative uptake and release

Lens compatibility testing:
EN ISO 11981:2009 - Ophthalmic optics - Contact lenses and contact lens care products - Determination of physical compatibility of contact lens care products with contact lenses