SPECTARIS Response to Public Consultation
Recast of the Medical Devices Directives
Unit ENTR F/3, Cosmetics and Medical Devices

SPECTARIS is the German trade association representing the National and International Companies of Contact Lens (and Lens Care) Manufacturers. It is residing in Berlin, Germany.

SPECTARIS welcomes the opportunity to respond to the Public Consultation on the Recast of the Medical Devices Directives

We believe that the consultation and subsequent recast of the Medical Devices legislative framework provides a valuable opportunity to strengthen the acknowledged aims of ensuring the functioning of the internal market and a **high level of protection of human health and safety**. From the perspective of the market for contact lenses, a high level of consumer protection is absolutely essential for consumer satisfaction and confidence. The Medical Devices legislation, appropriately revised, would provide the regulatory means of ensuring the highest level of consumer safety for contact lens users across the internal market. In particular, revision of the scope and requirements of the legislation, offers the opportunity to:

- **regulate non-corrective coloured/decorative contact lenses as medical devices; and**

- **ensure requirements for the safe distribution of all contact lenses**

QUESTIONNAIRE

1. Scope

Item 1: We object to consolidating the nine texts into one legal text because the impact of cost and time of administration changes in the Technical Documentation (e.g. references to the applicable Directive(s))are not outweighed by the perceived benefit of our members.

Non-corrective coloured/decorative contact lenses

Item 4: We believe that it is indeed necessary to ensure full protection of public health to **regulate non-corrective contact lenses (for cosmetic/aesthetic purposes) as medical devices**.

Recognizing that the scope of the MDD should be based on a risk-based classification approach, SPECTARIS asserts that non-corrective contact lenses should be regulated as medical devices because they possess an **identical risk profile** to corrective contact lenses which are correctly defined as medical devices. Indeed, non-corrective lenses can have a clear medical purpose such as the treatment of congenital or traumatic conditions,

albinism, or iris defects, iris colour mismatch, and are regulated as medical devices for such purposes or when they are also corrective.

The pre-marketing product safety and post-marketing vigilance requirements of the MDD with regard to corrective contact lenses suit perfectly the protection of health and safety of consumers using non-corrective contact lenses. The MDD already specifies the technical requirements that a contact lens has to fulfil, and these should be extended by analogy to non-corrective contact lenses. EN ISO 18369 Part I - Definitions – already makes no distinction between the two different types of contact lenses.

For manufacturers of both corrective and non-corrective lenses, there would be **no increase in the cost** of manufacturing because, currently in the EU, to the best of our knowledge, all manufacturers produce them to the same standard as medical devices. There may be cost savings as a result of reduced stock inventory, packaging and labelling for CE and non-CE marked products.

Regulating all non-corrective lenses under the Medical Device Directive contributes to **regulatory simplification.** This can be achieved by option 1, 2 or 3. A combination of Option 2 and 3 would be the most robust approach for contact lenses. As mentioned before, non-corrective contact lenses belong to the category of products which includes products with a medical purpose (Option 2). In addition, to avoid misinterpretation, we support listing these quasi-medical devices in an Annex to the future
Medical device legislation (Option 3). This also gives the flexibility to add new devices as they may become available. SPECTARIS is in favour of using the Comitology procedure to update the proposed list of quasi-medical devices.

SPECTARIS cannot comment on the socio-economic impact of option 1 because we are not in a position to speculate how this option would capture or exclude other types of products.
Since non-corrective lenses for cosmetic/aesthetic purpose, have the same risk profile but no medical benefit, the risk-benefit principle cannot apply as for regular medical devices. Therefore for quasi-medical devices, the principle of keeping the risk as low as reasonably possible (ALARP) should apply. Quasi-medical devices should be classified the same way as medical devices under the principles of Annex IX of Directive 93/42/EC to ensure a conformity assessment route that is equivalent to the risk associated with the device.

Item 5: **Counterfeiting of contact lenses and care products can put human vision and health at risk**, undermines customer confidence and trust in brands and has obvious negative impact on the legitimate business players; consequently it should be considered a criminal offence throughout the world, and punished accordingly.

The higher the number of trade layers and countries involved in the trade, the easier it is for a counterfeiter to place the product, cash in and then disappear. SPECTARIS supports measures for improved safety for the whole distribution chain.
It must be ensured that those involved the supply chain can ascertain that products meet the relevant essential requirements, are properly stored and handled, and that they can fulfil responsibilities in the area of field corrective action, ensure integrity of the supply chain to reduce the likelihood that counterfeited contact lenses enter the supply chain, and continued traceability is ensured.

3. Evaluation Procedures

Item 6: As far as performance of non-corrective contact lenses is concerned, there is **no need for additional or different essential requirements** from those existing for corrective contact lenses as they are essentially the same product. Since non-corrective lenses for cosmetic/aesthetic purpose have the same risk profile but no medical benefit, the risk-benefit principle cannot apply as for regular medical devices. Therefore for quasi-medical devices, a specific essential requirement for safety should be added to address the principle of keeping the risk as low as reasonably possible (ALARP).

Safe distribution of contact lenses

By establishing requirements for the safe distribution of all contact lenses on the basis of a professional's fitting, regular follow-ups and specification, **consumer protection** would be taken to an even better level, without limiting the consumer's choice of point of purchase and allowing competitive market forces play their important role.
A specification-based system has operated successfully since 2005 in the United Kingdom and since 2005 in the United States and provides a model of best practice for other Member States. It assures safety, while maintaining freedom of choice regarding the outlet or point of purchase. Although not included in the Agreement reached between the Council and Parliament, at the time of the revision of the MDD in 2006-2007, the Report adopted by the Environment, Public Health and Food Safety Committee of the European Parliament supported "necessary steps to ensure that sales of medical devices via the Internet, by mail order and other alternative distribution channels do not put the health and safety of consumers at risk" (Report A6-0332/2006). We hope that the Institutions will return to this issue in the forthcoming revision of legislation.

Indeed, Treaty Article 95 allows the EU to take harmonizing measures on public health issues, especially where disparities exist among Member States and where differences in national rules impact the establishment and functioning of the internal market. The requirement for some cosmetic products to be considered as for "professional use only" (Directive 2003/83/EC) is a precedent for safeguarding public health by specifying distribution conditions for certain products, while ensuring a free market in general. In this vein, amendment of the legislation to require Member States to **regulate the conditions of distribution of all contact lenses on the basis of a valid specification** would assure a safe distribution for these products and thereby would contribute to the attainment of a high level of human health protection.

Item 8: *Notified Bodies*

Proposal 1: We agree with proposals to increase transparency into activities of the Notified Bodies. It would need to be clear to whom an annual report by each Notified Body would be addressed, and how it would be structured and verified.
Proposal 2: We agree with developing improved information exchange from Notified Bodies to Competent Authorities.
Proposal 3: We agree with improving cooperation between Competent Authorities with regard to the activities of Notified Bodies.
Proposal 4: We would have thought that Member States can already impose sanctions and penalties where a Notified Body fails to act properly.
Proposal 5: We agree that the principle of 'forum shopping' is not acceptable. However, we are not aware of this practice being common for medical device manufacturers who typically have a greater interest in using an internationally recognised Notified Body. Manufacturers may want to use different Notified Bodies for different products because of Notified Body expertise regarding these products or for other reasons. It is particularly vital for the flexibility of the operation when one manufacturer is bought by another.

The suggested proposals should be coupled with greater monitoring by Member States (option 1) with a reporting mechanism to the Commission. The Commission should consider introducing the "peer review" principle whereby two Member States, one of which should be drawn from a list of experienced countries, would be involved in approving a Notified Body and periodically reviewing approvals.

SPECTARIS believes that Option 2 is less favourable, as it requires the set up of a whole new element of central administration. More clarification would be needed on how this new administration would work, such as the new legal framework, and the roles and responsibilities of the different parties. It is not immediately clear why this type of change would be needed.

Item 9: SPECTARIS strongly opposes the creation of a specific Committee in the EMEA on Medical Devices to examine these products. Instead, we consider it more appropriate to strengthen the oversight of Notified Bodies, as outlined in the proposals under Item 8.

Item 10: SPECTARIS strongly opposes the involvement of EMEA in the evaluation of medical devices on the grounds of cost, time and lack of expertise compared to the Notified Body route.

Item 11: It is not immediately clear to SPECTARIS what advantages will accrue from the proposal to use the EMEA instead of the current process. In particular, there is no obvious advantage to omission of the Notified Bodies from the control system on these medical devices. This means that there is no obvious advantage to us of Options 1 and 2 being applied and these would also result in the introduction of a different conformity assessment route that is not consistent with the New Approach. Options 1 and 2 are also not in line with the principle of mutual recognition which applies to medical devices.

SPECTARIS believe Option 3 would be the preferred option, as it stays in line with the New Approach principle that the Notified Body has the responsibility for the assessment of the files. EMEA is consulted on the products for which they have the competencies (pharmaceuticals per centralized procedure, blood derivatives). For other expertise, Notified Bodies would have these in-house or consult with other 'expertise' Notified Bodies (as mentioned under item 9).

Item 12: SPECTARIS does not oppose a more centralized approach of post-market surveillance but it should be clarified what the added value would be of giving this responsibility to EMEA.

4. Vigilance

Item 13: Proposal 1: professionals and consumers/patients may already report incidents which the manufacturer is required to record and follow-up in all cases

Proposal 2: **Notified Bodies already periodically review manufacturer's vigilance systems**. This involves an audit of the system for reporting incidents, as well as the information collected, and actions taken in response to all complaints, including detection of and corrective measures in response to 'signals'/'trends'.

Proposal 3 and 4: SPECTARIS is not opposed to a centralized system of notification of incidents on condition that the manufacturer would only deal with this centralized body, a single form is used and a single set of timelines. However, SPECTARIS questions whether EMEA would be appropriate for this task, taking into account associated costs, expertise and timelines.

Proposal 5: There does not seem to be pressing needs to change the current arrangements for medical devices. .
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5. Market Surveillance

Item 14: SPECTARIS supports the idea of a centralized registration system for medical devices provided that it replaces all national registration systems and at no cost, in particular the use of GMDN. We believe that EUDAMED should be the tool for this registration as opposed to EMEA.
The draft text of the New Approach addresses more stringent requirements regarding market surveillance. These need to be considered before putting new systems into place.

6. Borderline Cases

Item 15: SPECTARIS believes the CHMP, as it is currently established, does not have the relevant expertise to advise on the status of medical devices. If a Committee on Medical Devices is established at the EU level, it should be independent of the current committees within the EMEA.

7. GHTF

Item 16: Regulating non-corrective contact lenses as medical devices would assist international regulatory convergence since such lenses have been designated as medical devices by the US Food and Drug Administration in 2005.

8. Imports, Exports and Counterfeiting

Item 17: There should be improved **border controls**, **systematic checks** and use of Notified Bodies that are also approved and registered in the EU. This should be addressed in the new requirements from the New Approach.

Item 18: We would support treating contact lenses for export in the same way as contact lenses for the Community market. The **same standards** should be applied to contact lenses for the Community market and export markets.

Item 19: See also our response to Item 5: Counterfeiting of contact lenses and care products can put human vision and health at risk**.** There should be better **controls at customs** to avoid inflow of counterfeit goods (contacting the Manufacturer's Authorized Representative in the EU in case of doubt about a shipment), **sampling controls**, and stronger **criminal penalties**, including imprisonment, for those convicted of bringing on to the market and distributing/re-distributing counterfeits. The penalties, and cases of penalties imposed, should be made public and penalties should be related to the risk posed to the public (i.e. related to exposure and reach of products).

9. Simplification

Item 21: We would favour a Regulation in order to give legal certainty and consistency across the EU. For manufacturers, like SPECTARIS members, one legislative act is preferable to 27 transpositions. However, it is not clear how the specific requirements (such as languages and registration) will be covered. If these are not incorporated into the regulation, it could lead to even more confusion. SPECTARIS therefore welcomes the Commission's aim to simplify the legislation but asks that they ensure the specific requirements are clear, transparent and as easy as possible to follow.

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