European Federation of Precision Mechanical and Optical Industries

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Enhancing the health of the public European-wide and worldwide and facilitating innovation by harmonising the European and global regulatory environment

COMMENTS AND PROPOSALS TO THE STATUS OF A SOLUTION OF INDIGO CARMINE

DEFINITION OF MEDICAL DIAGNOSIS

EUROM VI welcomes the initiative of France to complete the enquiry regarding the status of a solution of indigo carmine (Annex 1). As far as the visualization of tissues or the mucosal anomalies (ulceration, fistula, irregular surface) is part of the diagnostic procedure, a classification of the solution of indigo carmine as a medicinal product according to Art.1, Para 2b) of the Directive 2001/83/EC (MPD) is applicable.

However, it should be considered that visualization of tissues or abnormal relief is not only done for diagnostic purposes, but also for an improvement and a simplification of surgical (therapeutic) procedures based on a previous diagnosis. Therefore, EUROM VI suggests to amend the outcome of the enquiry regarding the status of a solution of indigo carmine by adding the sub clause **within a diagnostic procedure**, in order to avoid regulatory unclarity:

Outcome

Detection by locating or making visible a suspect tissue or abnormal relief (ulceration, fistula, irregular surface) ***within a diagnostic procedure****, is considered as constitutes an in vivo diagnostic product. Thus, in accordance with point A.2.2.2 of MEDDEV 2.1/3, this product is not a medical device and is considered as a medicinal product.*

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Definition of the term "Medical Diagnosis"

As a matter of principle, it is difficult to reach a consensus on a specific issue, without clear definitions on regulatory terms. In fact, no legal definition of the term "*Medical Diagnosis*" is available up to now. By means of an amendment of the MEDDEV guidance document 2.1/3, rev.3, the Working Group on Borderline and Classification (WGBC) intends to overcome this ambiguity. Prior to the WGBC meeting scheduled for November 25th, 2015, the comments from the competent authorities and the industry in terms of the 1st proposal for a definition of "*Medical Diagnosis*" dated of March 13th 2013, have been forwarded to the stakeholders (Annex 2). In addition to these summarized comments, EUROM VI has forwarded an amendment to a definition and annotations on the term "Medical Diagnosis" to the stakeholders on April 29th, 2014 (Annex 3).

Taking into account the previous discussions in the WGBC meetings (e.g. in terms of Triamcinolone Acetonide used in intravitreal injection for visualization of ophthalmic tissues during a surgical procedure and AFL-HSA for fluorescence guided surgery of glioblastoma) and the necessity of an adequate healthcare, it becomes evident that the amendment of MEDDEV 2.1/3, rev.3 provides a good chance to permit innovative therapeutic options for the patients and the medical devices industry. Referring to AFL-HSA for the fluorescence guided surgery of glioblastoma the highest risk for the patients is a non-optimal surgical procedure leading either to tumor remission or to a loss of body function. These patients would not die from fluorescence (which per se is not critical) but from cancer. Please find more detailed information in Annex 4.

It appears inappropriate to adopt legal provisions from 1965 to new product groups in 2016. In fact, products consisting of substances for an *in vivo* medical diagnosis, e.g. radio-opaque substances, have been embedded into the MPD due to the lack of a legal framework for medical devices prior to the mid-nineties.

As the WGBC is not empowered to amend the MPD, the given definition of a medicinal product must be considered. However, the differentiation of the definitions "Medical Diagnosis", "Intra Surgical Visualization" and "Pure Visualization" is both comprehensible from the scientific point of view and convertible by the WGBC based on the authorization to suggest amendments for the MEDDEV guidance documents.

In this context EUROM VI appreciates the comments of the UK as given in Annex 2:

The UK would consider a definition of visualization separate to that of diagnosis, since visualization may be one aspect of the diagnostic procedure, but may also be used post-diagnosis as an aid in surgical removal of pathological tissue. A product is used for visualization if a morphological structure has been previously diagnosed, and the product is used only to assist proper treatment. These products should not be in the same category as products used for diagnosis, i.e, to identify the presence or absence of pathological tissues.

It can be summarized that substances for Intrasurgical Visualization and pure Visualization

- Have no safety issues
- Lead to a significant patient benefit (i.e. risk mitigation during and after the surgical procedure)
- Are innovative products to be developed by the medical devices industry based on a resilient regulatory framework
- Have a positive impact on health economy

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Therefore, EUROM VI applies to amend MEDDEV 2.1/3, rev.3 as follows:

A "**medical diagnosis**" is intended for the identification of a disease and the subsequent decision on the suitable therapeutic measurement.

The **intra surgical visualization** as well as the pure **visualization** is understood as a therapeutic measurement for a facilitated surgical procedure after a medical diagnosis and followed by an additional medical diagnostic assessment regarding the success of the surgical procedure and the decision on follow-up treatment.

Please note that definitions as suggested by EUROM VI fit into the proposed outcome for the status of a solution of indigo carmine as given above. Moreover, the regulatory status of medicinal products such as radio-opaque substances would not be affected, as they would still be used within the diagnostic procedure (e.g. an MRT).

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EUROM VI Medical Technology is the committee for Medical Technology within the European Federation of Precision Mechanical and Optical Industries and represents mainly European small and medium-sized enterprises.

The objectives of EUROM VI are:
- to represent European Medical Technology Industry;
- to promote cooperation between members but also with other European organisations;
- to encourage worldwide trade by being involved in harmonisation of legislation, standardisation, mutual recognition and certification procedures;
- to be a partner on works with the European Commission and Standardisation Bodies;
- to support European Industry views on international activities.