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 ON IMPROVEMENTS TO BE MADE FOR THE HELSINKI PROCEDURE

EUROM VI welcomes the request of DG GROWTH to submit proposals for an improvement of the HELSINKI PROCEDURE prior to the meeting of the Working Group on Borderline & Classification (WGBC), which is scheduled for November 25th 2015 in Brussels.

According to the introduction of the Manual on Borderline & Classification (MANUAL)[1], the primary aim of the WGBC which is comprised of Commission services, experts of Member States and other stakeholders (including industry and notified bodies) is to provide a forum to exchange opinions, and, possibly reach consensus in terms of borderline and classification cases. The MANUAL shall represent the views agreed in this group on products, or categories of products, which have raised doubts. This aim has recently been confirmed by Mr. Verheugen on behalf of the European Commission.[2]

EUROM VI appreciates the primary aim of the WGBC and acknowledges that the recent amendments of the HELSINKI PROCEDURE[3] already improved the approach, e.g. by means of defined timelines for a decision.

However, if the MANUAL shall represent the agreement of the WGBC in total, the availability of the same information for all members and stakeholders is crucial to secure a profound discussion, taking into account all relevant aspects, and to reach a reasonable and consistent agreement.

Currently, the competent authorities (CA) try to find a first opinion prior to involve other stakeholders, e.g. the industry and the notified bodies. By this, relevant product-related information for a reasonable decision might not be available for the CAs, running into the risk of inconsistent decisions.

Furthermore, all members of the WGBC should be entitled to vote, not only the CAs. In terms of innovation, new techniques and processes developed by the industry may not simply be sorted into

[1] http://ec.europa.eu/growth/sectors/medical-devices/specific-areas-development/index_en.htm#borderline
[2] http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2009-2170&language=EN
[3] http://www.eaarmed.org/wp-content/uploads/2012/06/Feb.-2013-SANCO-BC-05.doc

conventional demarcation and classification rules. As the patients as well as the health economics shall profit from this innovation, e.g. in terms of improved surgical procedures or with respect to the increasing need for the availability of self-medication, the WGBC being empowered by the COM to provide guidance documents to the stakeholders, should also use this mandate to overcome inappropriate provisions and to open new product opportunities for the patients and markets, respectively.

In terms of the voting itself, the provision that abstention (including non-responding CAs) shall be considered to be in agreement with the majority, does not appear to be reasonable, as in particular non-responding to a request may have various reasons. **EUROM VI** suggests that a majority of 75% shall be reached by the responding members including all stakeholders that do not abstain. Any refusal of a draft text should be scientifically justified in written form and should be on the Agenda of the subsequent WGBC meeting again.

Summarized, **EUROM VI** suggests to improve the current HELSINKI PROCEDURE by

i) the involvement of all members and stakeholders of the WGBC from the beginning;
ii) the right to vote for all members and stakeholders of the WGBC;
iii) the limitation for a decision to effective votes, whereas abstention or non-responding is not included.

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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.