Comments to COEN GUIDE Implementation of the CMC Decision No. 3 – provided by EUROM VI Medical Technology Date 19/04/2012

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	From[1]	**Line / No. / …**	**Type[2]**	**Comment and rationale / justification for proposed change**	**Proposed revised text**	**CMC/COEN assessment**
1	EUROM VI		G	EUROM VI welcomes the opportunity to provide comments on the COEN Guideline "Implementation of the CMC Decision No. 3". However, EUROM VI would also like to express its disappointment that industry's concerns regarding the content of the CMC Decision No. 3 have not been taken into account.		
2	EUROM VI		G	The need for specifying the manufacturer's detailed physical address including street and no. is still not really clear, as long as the manufacturer (and not a sales office or a call center) can be contacted at his registered place of business via the address information provided on the medical device, its packaging, and, if applicable, on the instructions for use. Further, CAs have access to the manufacturer's detailed physical address by means of the registration data in EUDAMED.		
3	EUROM VI	30 …31	T	The request for full address information including street and no. disregards a German peculiarity of postal codes: Postal customers in Germany with high mail volumes ("*Großkunden"*) have their own postal codes ("corporate codes"), separate from those used for postal districts or PO Box number ranges. Corporate postal codes are directly related to a physical address and allow the identification of the manufacturer's physical address without specifying street and no. Making use of the corporate postal code is the fastest and safest way to contact the manufacturer in writing.	To amend lines 30/31 as follows: The address must be a complete street address. Not a URL, an e-mail address or post office box or postal code, if it does not enable the identification of and the physical contact with the manufacturer.	
4	EUROM VI	36 … 46	T	This request disregards the fact that there may be limitations by product size or label size, so that placing all requested address information may not be possible in some cases. Although communicated from CAs to industry after publication of the CMC Decision, the acceptability of the full address on the instructions for use only and abbreviated address information on the medical	To amend line 46 as follows: Abbreviated address information shall be regarded acceptable if the full address information is provided either on the device label, or on the instructions for use, or on the packaging label.	

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				device and/or on the packaging label is not contained in the proposed Guidance document. (See also comment no. 7)		
5	EUROM VI	63 (also 58/59 151)	T	The envisaged transition deadline (2012-09-01) for implementation of necessary measures is not acceptable for industry, especially when taking into account the legal status of the CMC Decision No. 3, and how it was communicated to individual manufacturers. We doubt that actually all manufacturers have been informed officially. Depending on the number and complexity of products, it may take a manufacturer much longer than 2012-09-01 to change the labels of all his affected devices (note: changing labels requires revising, releasing and approving all corresponding technical drawings and bills of materials, possibly test protocols and related templates, procuring new labels and introducing them into the manufacturing line).		
6	EUROM VI	107… 110	T	The proposed measures of the competent authorities do not differentiate between medical devices manufactured after this deadline, or medical devices manufactured before, (i.e. under application of the harmonized standard EN 1041:2008-11). As relabeling all medical devices on stock would constitute a tremendous and disproportionate effort for the manufacturers concerned, relabeling medical devices already on stock before the deadline, should not be required as long as the labeling deviating from the CMC decision does not pose a risk to users or patients.		
7	EUROM VI	125 … 128	T	The answer to Q2 “MDD: The label and the instructions for use must bear the (trade) name and address of the manufacturer.” is not fully correct. The MDD, Annex I, 13.1 reads: *Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer.*	To amend lines 120 … 123 as follows (IVDD is similar): MDD: <u>As far as practicable and appropriate</u>, the label and the instructions for use must bear the (trade) name and address of the manufacturer. …	

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				This information comprises the details on the label and the data in the instructions for use. *As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices.* The MDD differentiates between the label and the instructions for use regarding the information to be provided by the manufacturer, and requests to have this information (including the label!) on the device itself only as far as practicable and appropriate. This fact has been disregarded by the CMC Decision and the proposed COEN Guide.		

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