Comments on WHO Working Document QAS/16.664
Title of the document: WHO Global Model Regulatory Framework for Medical Devices including IVDs

Comments submitted by : Institute for Quality and Efficiency in Health Care (IQWiG)
Telephone number : +49 (0)221/35685-4
Address : Im Mediapark 8, 50670 Cologne, Germany
Email : nmv@iqwig.de

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General comment(s) if any :	Originator of the comments
We support the idea of providing a general regulatory framework for medical devices, which can be used as a basis for establishing regulatory systems in countries where such systems are currently missing. As is (indirectly) stated in the introduction (page 1), the aim of any government in this context is "to give citizens justified confidence in medical devices used in their countries". However, in the current version of the text, the requirement to provide data on (clinical) efficacy / effectiveness of a medical device to gain market access – which is a prerequisite to ensure patient safety (and thus confidence in medical devices) – is not clearly described. Thus, we recommend giving this aspect more emphasis throughout the text.	
The Council of the European Union has very recently published the "Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009" (http://data.consilium.europa.eu/doc/document/ST-9364-2016-REV-3/en/pdf). Because this consensus will form the basis of future EU regulation, key terms and concepts should be updated using this source. Specifically, the terms "clinical evidence" and "clinical benefit" should be borrowed from the EU regulatory texts.	

# section	Line no.	Comment / Rationale	Proposed change / suggested text	Classification **L**= low **M**= medium **H**= high	Originator of the comments (for WHO use)
2, page 10	28	In the text it is written “definitins”. This is a typo.	Correct: “definitions”	L	
2, page 12	12-13	It seems that within this section there is no difference in meaning between the terms “performance” and “effective”. However, in our understanding, performance does not comprise anything regarding the efficacy and/or effectiveness of a medical device.	Please specify “performance” and “efficacy” / “effectiveness” (at least in Annex 1).	H	
2, page 12	27	The text contains the misspelled word “assesment”.	The typo should be corrected.	L	
2, page 12	35-36	It is a general principle in medical device regulation that “risks should be minimized and weighed against the benefits”. However, the risks of a new device are crucially dependant on invasiveness and novelty of the new device. This principle should be mentioned here, as it strongly guides regulatory requirements. Surprisingly, the current version of the text does not discuss the concept of substantial equivalence or analogous medical devices.	An additional principle should be added: “The risks of a new device are determined by the class of the new device and the degree of similarity between new and predicate device. Thus, the requirements regarding performance, safety, and clinical efficacy should be the higher, the more invasive and the newer a device is.”	M	
2, page 12	37-38	It is correctly stated that medical devices must conform to the requirements for “safety, efficacy and quality, including clinical evidence”. However, “efficacy” is inadequately described.	The requirement for efficacy should be specified. Further, demonstration of efficacy should be added as a basic requirement for market access throughout the text (rather than safety and performance only). A definition for efficacy should also be added to Annex 1.	H	
2, page 13	17	Needles are given as an example for class A medical devices.	Please check classification rules. Needles should be classified as class B devices, since they are invasive (see Rule 6 of GHTF medical devices classification document). Syringes without needles are class A.	H	

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3, page 20	23-30	While the mentioned skills and competencies in this paragraph should indeed be available in any regulatory body related to medical devices, it is also essential to have clinical expertise. This is only partly mentioned in the current version of the text on page 36 ("advice from external experts").	We suggest adding "clinical professionals" to this paragraph (as in house experts). In addition, clinicians should also play a role as external advisors (see page 21 and 36). Another reason for permanently employing medical doctors at a regulatory body results from the fact that a regulatory body is responsible for approval and monitoring of clinical investigations (page 33, line 3-15). On a side note: The two references cited in this paragraph (and also reference 15) refer to information provided by the Regulatory Affairs Professional Society (RAPS) (commercial online course or unpublished data). We suggest adding references, which are publicly available (and at no extra costs). RAPS seems to focus on regulatory experts in the industry sector, which can explain the skills described in this paragraph.	H	
Annex1		Definitions for safety, performance and efficacy are missing.	Demonstrating safety, performance and efficacy are crucial requirements for market access and thus these terms should be defined.	H	
Annex 1		Definition of clinical performance is restricted to IVD.	Definition should be broadened and cover any medical device. In addition, the term "clinical benefit" might be useful.	M	