

UK Public Consultation on New Medical Device Legislation

The UK Medicines and Healthcare products Regulatory Agency launched a public consultation in November 2012 that presented its views and requested opinions from stakeholders on the newly proposed medical device legislation. Readers should review the consultation document and summary of responses when they become available.

Maria Donawa

On 26 September 2012, the European Commission adopted a proposal for the regulation of medical devices¹ containing 97 articles and 16 annexes and a proposal for the regulation of *in vitro* diagnostic (IVD) medical devices² containing 90 articles and 14 annexes. Certain aspects of the medical device proposal were covered in a previous article.³ It stated that prudent medical device companies should keep a very close watch on the review process by the European Parliament and Council that will lead to a common position and subsequent final wording. Furthermore, it was suggested that, where possible, companies should make their views known, for example, through industry associations, if they believe that the proposed revision is likely to be more detrimental than beneficial to European citizens. This indirect route for making stakeholder views known on such critically important legislation is far from ideal and ironically lacks the transparency that the proposals espouse.

In 2008, stakeholders were given the opportunity of commenting on a European Commission public consultation document,⁴ containing background information and a series of questions related to such issues as the scope of the directives,

reinforcement of the Essential Requirements and strengthening of evaluation procedures for the highest risk devices, the possible involvement of the European Medicines Agency in the control of medical devices and increasing the effectiveness of vigilance and market surveillance. In 2010, the European Commission launched a public consultation⁵ on specific issues related to the European regulation of IVD devices, seeking comments on such issues as classification, conformity assessment, legislative scope and clinical evidence.

Although the European Commission can be applauded for the management of the public consultations held in 2008 and 2010, the regulatory detail of the consultation documents, which were really only concept documents, pales in comparison with the exceedingly detailed text contained in the proposed medical device and IVD regulations. It is also interesting to note that the European process of adopting final versions of the device regulations is in stark contrast to the process in the United States, where new regulations and even guidance documents are published as proposed regulations and draft guidance documents, respectively, to allow public comment to be provided and seriously considered during the process of developing the final documents.



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UK provides opportunity to comment

On its website at www.mhra.gov.uk/Publications/Consultations/Deviceconsultations/CON205361, UK MHRA announced that they launched a public consultation on the revision of European legislation on medical devices.⁶ The consultation was launched in November 2012 and lasted 10 weeks. It stated that it was seeking the views of healthcare professionals, patients, industry, academics, and the interested public on the draft new European legislation on medical devices. It also explained that the public consultation set out what the MHRA thinks about the different changes suggested by the European Commission and that it wanted to hear “your opinion on how the new legislation will have an impact on you and how you think that it can be improved.” A video on the website presented a useful and concise overview of the public consultation. The deadline for providing responses to the consultation was no later than 21 January 2013. The MHRA plans to publish a summary of responses by the end of March 2013.

In addition to the main public consultation page, “New legislation on medical devices” at www.mhra.gov.uk/Howweregulate/Devices/NewLegislationonMedicalDevices/index.htm links to a brief overview on the revision of the medical device directives, why the legislation is being changed and the stages and timelines associated with the regulations coming into force. In the last section of the overview, “How can I get involved,” the MHRA states that it is currently formulating its opinion on the proposed regulations and that it is essential that it obtain views from patients, healthcare professionals, industry and academics. This will be accomplished by the public consultation, starting conversations on the MHRA Facebook page about the most important elements of the proposed changes and speaking with stakeholders at meetings or events during the public consultation period, where stakeholders believe that would be helpful and as far as other commitments allow. Information on getting in touch with members of the European Parliament is also provided, along with contact information for the MHRA officials who are leading the work on the new proposals within the agency.

UK public consultation document

Anyone interested in understanding the implications of the proposed medical device regulations or how a Competent Authority views the proposals should download and carefully review the UK

public consultation document. It is 51 pages long, covers all 10 chapters of the two proposed regulations on medical devices and IVDs, and includes 68 questions in total, spread throughout the document, and aimed at obtaining stakeholder opinion on whether they agree with the MHRA position on a particular aspect of the proposed regulations. It should be mentioned that each proposed regulation has the same number of chapters, where only two differ slightly with regard to their titles.



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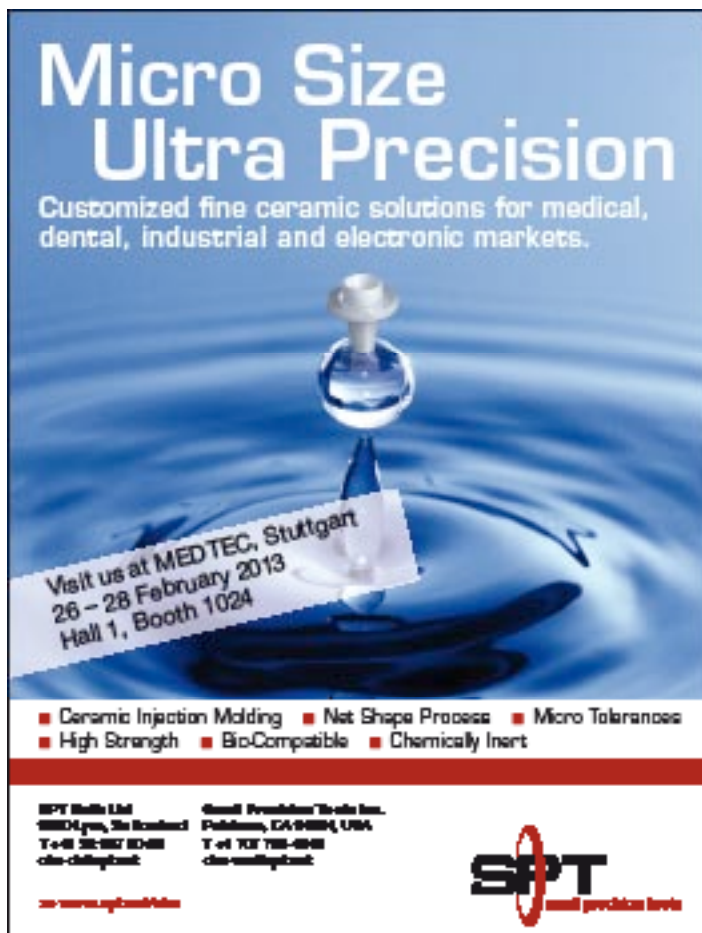
The consultation document is structured to facilitate review, in that each section contains:

- general points about the proposed changes in the medical device and IVD regulations;
- reference to the specific article in the regulation that contains the full text under discussion; and
- a section of bordered text outlining the MHRA position and specific questions on whether stakeholders agree with the position, and if not, why not.

For example, section 1.3 of Chapter I: Scope and definitions, of the consultation document discusses an interesting and important proposed change in the medical device regulation. This proposes that devices composed of substances or combinations of substances intended to be ingested, inhaled or administered rectally or vaginally that are absorbed by or dispersed in the human body are within the scope of the regulation. Annex VII of the proposed regulation, which sets out the classification criteria for medical devices, classifies these devices as Class III.

The MHRA intends to use the information gained from the **public consultation process** to negotiate with other European member states and the European Parliament.

The MHRA position is that clarifying the scope of the medical device regulation is generally helpful and clarifies which products fall under the legislation and which do not. However, the MHRA position is that it prefers to exclude products composed of substances or combinations of substances that are intended to be ingested, inhaled or administered rectally or vaginally that are absorbed by or dispersed in the human body from the regulation of medical devices. That is, the MHRA states that it has concerns that medical device legislation does not fully take into account the safety aspects of these products. In particular, it goes on to say that these products may significantly affect the safety or efficacy of the medication with which they are taken, and special consideration needs to be given to the use of these products in certain patients, such as children or those with compromised renal or hepatic function. Therefore, MHRA believes that these products should be excluded from the scope of this regulation and be regulated under European medicines legislation.



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Thus, two questions were posed to stakeholders. Question 1 was, “Do you agree with our proposed position? If not, please explain why.” Question 2 was, “What impact do you think excluding the products composed of substances or combinations of substances that are intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body from the scope of the medical devices regulation would have? For instance, might some very low-risk products be inadvertently excluded from device legislation?”

Readers should refer to the public consultation for the full text of the MHRA position on this and other changes for which MHRA expresses an opinion and requests comments. Even though the deadline for comment may have passed, reviewing the consultation document provides a useful opportunity for gaining a better understanding of the newly proposed legislation.

After the UK consultation

The MHRA intends to use the information gained from the public consultation process to negotiate with other European member states and the European Parliament. In this regard, the MHRA states that it is keen to receive analysis and evidence that will help the agency achieve its negotiating objectives. Furthermore, it states that stakeholder input will be crucial to help

MHRA identify the full implications of the changes and areas of concern. Stakeholder input from a European consultation would have served the same critical purpose.

References

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