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Cover story : The Fututre of Clinical Evidence Requirements For Medical Devices in the EU

By A Wenzel adapted from an article in scrip regulatory

The Council of the European Union's agreed amendments to the requirements for clinical evaluation reports under the new Medical Device Regulation are substantial. And so are its proposed amendments to clinical investigations and post-market clinical follow up. Sarah Sorrel explains why these amendments are likely to become reality, how companies may be required to adjust and what demands they will have to meet.

The proposed changes made by the Council of the European Union's Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) in June to the European Commission's texts for a Medical Device Regulation are intended to raise the bar for obtaining the CE marking, both in terms of quality and quantity of clinical data for all devices[1].

If adopted, they will create potentially complex and costly new measures for all parties concerned – manufacturers, notified bodies and competent authorities (CAs).

The most burdensome proposed changes are for manufacturers of high-risk devices (implantable and Class III) with the need for more clinical investigations and the introduction of an additional so-called scrutiny procedure by an "expert panel" independent of the notified body.

Below are some of the key changes that would have an impact on manufacturers in terms of cost and timing of CE marking should the council amendments make it through the regulatory adoption procedure – a process which EU experts predict will be completed by the first half of 2016.

A. An "Expert Panel" To Scrutinize and Advise On CE Marking

By far the most significant and burdensome change in the proposed regulation for implantable and high-risk devices is the introduction of an additional "scrutiny procedure" by an "Expert Panel" prior to CE marking. The panel may also be consulted in advance of CE marking for advice on the clinical development plan. This would institute a mechanism for manufacturers to seek scientific advice at the European level prior to conducting clinical investigations to ensure that the clinical data will meet the requirements of the regulation.

B. Modified CA Approval Procedure and Timelines

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One of the most extensive changes proposed by the council concerns the notification procedure for clinical investigations of non CE-marked devices.

At present, this notification procedure is different in each EU member state without exception, making the process very complicated, especially for multicenter trials involving several member states. Many countries have a specific application form that is different from one country to the next, and that needs to be filled out in the local language. Germany, for example, requires a full copy of all pre-clinical reports whereas summary reports are acceptable by others.

Timelines also differ. In some countries, the process can be carried out in parallel with the ethics committee procedure. The shortest timeline is in France where approval is possible in 60 days if there are no questions. In other countries such as Poland, the two procedures are sequential. Furthermore, as Poland requires a signed contract before making a submission to the ethics committee, timelines can easily extend to six months. Needless to say, the current situation is very complex and labor-intensive for manufacturers.

C. Clinical Study Reports To Be Publicly Available Before CE marking

This is a significant change compared to the current EU regulatory system which is totally opaque with regard to the clinical data that is used for CE marking. Presently, competent authorities may request a copy of the final report individually, but there is no mechanism for sharing the information amongst CAs, and the information is not public unless it results in a scientific publication. Under the proposed regulation, the clinical study report and its summary would have to be uploaded in the European electronic database to be viewed by all, including the public – and this is prior to CE marking. This is akin to a system currently in force in France where clinical evaluations for reimbursement approval of medical devices are posted on the website of the Haute Autorité de Santé (www.has-sante.fr).

Although there are a lot of changes to the clinical aspects of the CE marking process, especially for implantable and Class III devices, most are needed and reasonable if the system is to be maintained. Some changes will actually streamline the process such as the proposed CA notification process for clinical investigations. The details concerning the Expert Panel are still an important unknown. However, on balance, Europe will remain an attractive location for development, CE marking and initial launch of new medical technology.

This story has also been published in Clinica Medtech Intelligence*. Scrip Regulatory Affairs brings selected complementary coverage from our sister publications to our subscribers. The Author is Sarah Sorrel from MedPass International.*

References

1. EU medtech reform makes landmark move, *Scrip Regulatory Affairs*, 19 June 2015

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No. 1

1. Using Pre-Submission Meetings to De-Risk Medical Devices Applications

By A Wenzel adapted from an article in scrip regulatory

As medical device regulators around the world continue to raise the bar for regulatory compliance and usher in new requirements, companies can find the product approval process overwhelming and intimidating.

One solution for companies looking to make the submission process run more smoothly would be for them to meet with the regulators before they submit a formal marketing application by requesting a pre-submission meeting, says Arthur Brandwood, CEO of medical device consultancy firm Brandwood Biomedical. Pre-sub meetings give medical device companies the opportunity to better recognize issues about a product that matter to a regulator and also to understand the expectations regulators might have on how companies should deal with those issues, says Brandwood. To ensure that companies make the most of a pre-sub meeting, it is important that they ask the regulators the right questions, he says.

Pre-sub meetings are offered free of charge by most regulatory agencies, Brandwood says. He suggests that medtech companies make optimal use of this service as it would help minimize the possibility of a failed application or the need for generating last minute data to fill gaps.

US

The FDA has detailed guidance on how it handles requests for pre-submission meetings[1]. Among other things, a request for a pre-sub meeting should include a description of the device, which should be sufficiently detailed for the FDA to understand the aspects of the technology to be discussed in the pre-sub meeting. Brandwood suggests that companies should include a video about the device, if it is appropriate. "For example, if you have a new implant which uses a new surgical technique then send them a video of the surgical technique. It's helpful to give as much information about the device as you can," he says. Also, the application for a pre-sub meeting should state the proposed intended use of the device and its indications. "This is really important… All of the discussion [at the pre-sub meeting] will be within the context of the intended use and if you change it later, then you risk invalidating the consensus from the discussion, and you may need to start again," Brandwood says.

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There is no fee associated with FDA pre-sub meetings, and companies typically get a meeting date within three weeks of filing a request. The meeting itself occurs within 75 days of filing a request, and a close out is within 90 days. Brandwood points out that the FDA tends to beat these deadlines, which means meetings tend to be earlier and closed out sooner.

EU

In the EU, there is no formal process for pre-submission meetings but most notified bodies tend to engage in a pre-contract discussion with medtech companies to understand what the technology involves. The pre-contract discussion gives a company the chance to ask notified bodies specific questions on whether their proposed approach provides a valid basis for conformity assessment review," says Brandwood. It is important for companies to understand that notified bodies are not consultants. "The European Commission has been very strict in recent years about notified bodies not being allowed to consult. They don't want to be seen as consulting by providing direct consulting advice in these pre-contract discussions, but they will give feedback on your proposals," Brandwood explains.

Australia

Australia's Therapeutic Goods Administration has informal arrangements in place for pre-submission meetings. The service, which is free of charge, is only offered for devices for which the TGA directly conducts a conformity assessment, and not for devices where it accepts the EU conformity assessment certificate in lieu of direct assessment. Companies looking for a pre-submission meeting with the TGA should approach the agency prior to filing the conformity assessment request, Brandwood suggests.

China

There are two opportunities for pre-submission meetings with the China Food and Drug Administration. The CFDA has a weekly arrangement – called Open Thursdays – where anybody can come to the agency on a Thursday and ask questions about a proposed submission to whoever is on duty on that day. "It's informal. Obviously, you are not going to get a major insightful review, but you can deal with particular questions and get some worthwhile advice by doing that," says Brandwood. As Open Thursdays are quite busy, he suggests that companies get there early, take a number and wait in a queue. It is also possible to have a more detailed discussion with the CFDA, but the company should have a good reason for this, ie they should request a meeting on a specific issue that can only be resolved by a face-to-face discussion. Brandwood suggests using a consultant for this, who can help identify the right division and the right review branch.

References

1. US FDA improves and expands early feedback mechanisms for medtech, *Scrip Regulatory Affairs*, Feb. 19, 2014

Source: *Vibha Sharma* , Scrip Regulatory

2. EMA: Making IT services for medicines regulation in Europe more efficient

By A Wenzel adapted from press release of EMA

EMA Management Board and Heads of Medicines Agencies endorse EU Telematics Strategy and Implementation Roadmap 2015-2017

The European Medicines Agency (EMA) Management Board endorsed the European Union (EU) Telematics Strategy and Implementation Roadmap 2015-2017 on 6 August 2015 that had already been adopted by the Heads of Medicines Agencies in July 2015.

The roadmap provides a concrete outline of the EU Telematics strategy and its implementation from 2015 to 2017 describing how specific projects will address the information-technology (IT) needs arising from European pharmaceutical policy and legislation.

The work of the EU medicines regulatory system in promoting and protecting public health is underpinned by common IT services - which are put in place and maintained by EU Telematics. EU Telematics facilitate efficient and effective coordination and exchange of information on medicines between EMA, the European Commission and the national competent authorities for medicines regulation in the EU.

Projects included in the roadmap cover areas such as governance structure implementation, clinical trials regulation, management and processing of electronic submissions for marketing-authorisation applications and safety information on human and veterinary medicinal products, data integration and pharmacovigilance.

The roadmap published today builds on the EU Telematics Strategy 2014-2016, which was endorsed in 2014.

The overall implementation framework is expected to benefit by maximising the efficiency of IT communication across the EU regulatory network and will be regularly updated as the programmes evolve.

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3. WHO Makes Progress On Updated Model Regulations For Medtech

By A Wenzel adapted from an article in scrip regulatory

The World Health Organization is making progress on developing a revised model regulatory framework for medical devices for national agencies that face resource constraints or have yet to develop or implement device regulations in their respective jurisdictions.The updated framework, which will be issued in the form of a guidance document, is expected to be ready for stakeholder consultation in around nine months' time. Once finalized, the guideline will be recommended for adoption during the 2016 WHO expert committee meetings.The new model framework will offer a stepwise approach explaining how national regulatory agencies should implement the regulatory framework, including the administrative framework, to ensure the quality, safety and efficacy of licensed medical devices. It will also explain how agencies should authorize the withdrawal of unsafe and falsified medical devices from the market, Hansen told *Scrip Regulatory Affairs*.

Earlier this year, the WHO gave a presentation on the model framework at a meeting hosted by the International Medical Device Regulators Forum[2]. At the meeting, the WHO explained that the framework would cover, among other things:

- definition of a medical device;
- medical device product cycle ;
- guiding principles on developing a risk-based model for market access, conformity assessment process, and vigilance activities;
- critical elements for regulating medical devices, eg regulatory system, import controls, distribution channel control etc; and
- phases of regulatory implementation.

The guidance on the model regulatory framework will be advisory in nature, unless a member state decides to make it legally binding.

National Regulatory System assessment tool

In addition, the WHO is planning to engage medtech regulatory experts in early autumn in efforts to revise its national regulatory system assessment tool, which is used to identify gaps and develop strategies to improve and support national regulatory agencies. The assessment tool is already in place for medicines and vaccines and it is used by the WHO to regularly assess the capacity of national regulatory authorities to regulate these products. The goal is to harmonize this tool for other health product streams, such as medical devices (including IVDs), blood products and traditional medicines.

In the first week of December, an international consultation will take place to discuss the harmonized tool for all health product streams, Hansen said. The revised assessment tool will include indicators for each product stream, including medical devices.

References

1. Medical device regulations, global overview and guiding principles, 2003, www.who.int/medical_devices/publications/en/MD_Regulations.pdf

2. WHO presentation at IMDRF meeting in Tokyo, Mar. 24-26, 2015, www.imdrf.org/docs/imdrf/final/meetings/imdrf-meet-150324-tokyo-presentation-update-who.pdf

Source: *Vibha Sharma* , Scrip Regulatory

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4. Saudi FDA Explains Pre-Screening Of Promotional Content For Medical Devices

By A Wenzel adapted from an article in scrip regulatory

The Saudi Food and Drug Authority has issued final guidance explaining its requirements for pre-screening advertising and marketing material relating to medical devices[1].

The guideline states that all promotional content relating to a device – including product brochures and catalogues, publications in technical magazines, written material in newspapers and professional magazines, exhibition material and information to be presented at medical lectures, and on the television, radio and internet – must be vetted by the Saudi FDA before it is used.

The agency explains that it pre-screens and approves such content to ensure that any performance or safety claims regarding the device are consistent with the terms of the marketing authorization. It requires documentary evidence in support of all claims (eg, faster or better) used for promoting a device.

The promotional content can be submitted for pre-screening either:

- by the manufacturer as part of the medical device marketing authorization (MDMA) procedure. In such cases, the advertising and marketing material is prepared and submitted by the local manufacturer (or prepared by a foreign manufacturer and submitted by its authorized representative). Promotional material can be submitted as part of the marketing authorization application or after the device has been authorized to be placed on the market[2]; or
- by licensed distributors or registered healthcare facilities. In such cases, the Saudi FDA would issue a medical device advertising license (MDAL) to the applicant. While the Saudi FDA has not specified any timeline for handling such cases, the agency is expected to take two to four weeks to pre-screen and approve advertising materials under this process, says Jamil Arif, manager (Medical & Scientific Division) at consultancy company Bio-Standards. The MDAL process is meant for licensed distributors or registered healthcare facilities that prepare and submit advertising and marketing material on their own behalf. In cases, where the promotional material is to be used as a presentation at a medical lecture, seminar or workshop, the applicant is required to provide a copy of the presentation, hall reservation and the speakers' CV. Arif explains that the MDAL process was created as healthcare facilities, who conducted medical education seminars, "were concerned about the authentication of the advertising material used by the distributors during such marketing activities".

The guideline states that advertising and marketing materials should in English if intended for professionally qualified persons, and in Arabic if meant for laypersons. Also, it states that any modification to an approved promotional content, including changes introduced due to translation, would require a new approval.

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1. Guidance on Medical Devices Advertising Requirements (MDS – G11), posted online 31 August 2015, www.sfda.gov.sa/en/medicaldevices/regulations/DocLib/Guidance%20Document%20-%20Advertising%2027-08-2015%20v1.pdf

2. FAQs: What can the manufacturer provide when the product has no market literature? Site accessed Sept. 4, 2015, www.sfda.gov.sa/en/medicaldevices/about/Pages/faqs.aspx

No. 5

5. Canada Finalizes Changes to Recognized Medtech Standards List

By A Wenzel adapted from an article in scrip regulatory

Health Canada has updated its list of recognized medical device standards with 27 new entries[1]. The agency has also removed 17 standards from the list and replaced nine recognized standards with their newer versions.

The agency had consulted on these changes in May[2]. The only change to the final list compared to what was proposed in May is the addition of Canadian standard CAN/CSA-C22.2 NO. 60601-1:14 - Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. This is the third edition of CAN/CSA-C22.2 No. 60601-1, which is an adoption, with Canadian deviations, of the identically titled IEC standard[3].

Health Canada's updated list of recognized standards came into effect on Aug. 31.

References

1. Health Canada, List of Recognized Standards for Medical Devices, Aug. 31, 2015, www.hc-sc.gc.ca/dhp-mps/md-im/standards-normes/md_rec_stand_im_norm_lst-eng.php

2. Canada consults on recognizing 26 new medical device standards, *Scrip Regulatory Affairs*, May 8, 2015

3. CAN/CSA-C22.2 NO. 60601-1:14, site accessed Sept. 15, 2015, http://shop.csa.ca/en/canada/applications-of-electricity-in-health-care/cancsa-c222-no-60601-114/invt/27000642014

Source: *Vibha Sharma* , Scrip Regulatory

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No. 6

6. US FDA Launches Patient Engagement Advisory Committee For Devices

By A Wenzel adapted from an article in scrip regulatory

The US Food and Drug Administration is setting up a Patient Engagement Advisory Committee to help the agency incorporate the needs and experiences of patients into its regulatory decisions for medical devices and diagnostics[1].

The new committee, announced Sept. 18, fits along with the broader patient preference initiative at the FDA's Center for Devices and Radiological Health. CDRH Director Jeff Shuren publicly discussed plans for the advisory panel at a September 2013 meeting[2].

"FDA believes that patients can and should bring their own experiences to bear in helping the Agency define meaningful benefits or unreasonable risks for certain devices," said Nina Hunter, a regulatory scientist in FDA's device center[3].

Tradition Of Patient Input

According to Kathryn O'Callaghan, CDRH's associate director for science and strategic partnerships, device-makers have a stronger tradition of incorporating patient preference compared to drug makers because medical devices are "something you can build." There are several places along the device development pathway where a device can be tweaked based on patient input, she noted.

But more feedback from patients is needed, O'Callaghan believes. More patient input is needed, especially for the growing field of home-use devices and on questions of what patients think matters most in evaluating treatment options. The information is most important for treatments for conditions that are especially sensitive to patient preferences, such as obesity.

CDRH has seen a sharp upward jump in the number of applications including patient preference data in recent years. Before 2009, only about 20 submissions per year included patient-reported outcome measures. But after the agency began publicly discussing the issue, that jumped to 120 in 2014. O'Callaghan expects the number to continue to grow in the wake of a May 2015 draft guidance encouraging manufacturers to begin submitting patient preference data[5].

Term Limits, Topics For Panel's Purview

Rather than focusing on a product or specific disease, the new patient advisory committee, which will include nine voting members who will serve on overlapping terms of up to four years, will be asked to weigh in on a variety of important patient-related issues, the agency said. FDA

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hopes the committee will identify new approaches, promote innovation and identify unintended consequences that could result from FDA policy.

Potential Nominee Qualifications

Committee members are to be "experts who are knowledgeable in areas such as clinical research, primary care patient experiences, and health care needs of patient groups in the US."Selected committee members may be experienced in the work of patient and health professional organizations; methodologies for eliciting patient preferences; and strategies for communicating benefits, risks and clinical outcomes to patients and research subjects.One patient advocate already told *Scrip Regulatory Affairs* sister publication *The Gray Sheet* that she was nominating herself to sit as a voting member on the panel – Joleen Chambers, a patient advocate for the Failed Implant Device Alliance, who maintains a FiDA blog.

Two other nonvoting members will sit on the PEAC – a consumer representative and an industry representative, as detailed in a separate *Federal Register* notice[7].

References

1. *Federal Register*, Establishment of the Patient Engagement Advisory Committee, Sept. 21, 2015, www.gpo.gov/fdsys/pkg/FR-2015-09-21/html/2015-23521.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery
2. US FDA explores giving patients a better voice in devices benefit-risk decisions, *Scrip Regulatory Affairs*, July 29, 2013
3. FDA Voice blog, Sept.18, 2015, http://blogs.fda.gov/fdavoice/index.php/2015/09/fda-announces-first-ever-patient-engagement-advisory-committee/
4. Drug industry needs to 'catch up' with regulatory innovations, *Scrip Regulatory Affairs*, June 15, 2015
5. US FDA consults on using patient experience to support approval of novel devices, *Scrip Regulatory Affairs*, May 19, 2015
6. FiDA blog, website accessed Sept. 23, 2015, http://fida-advocate.blogspot.co.uk/
7. *Federal Register*,Request for Nominations of Individuals and Industry Organizations for the Patient Engagement Advisory Committee, Sept. 21, 2015, www.gpo.gov/fdsys/pkg/FR-2015-09-21/html/2015-23522.htm

Source: *Sue Darcey and Elizabeth Orr* , Scrip Regulatory

No. 7

7. EU Council Settles Medtech Reform Position: Let The Trilogues Begin

By A Wenzel adapted from an article of Scrip Regulatory

The Council of the European Union has set out its own position on the proposed EU medical device and IVD regulations - the MDR and IVDR - enabling the EU institutions to begin their three-way debate on the twin regulations[1]. The first 'trilogue' discussions involving the council, the European Parliament and the European Commission are due to be held on 13 October.

COREPER, the Committee of the Permanent Representatives of the EU member states, approved the Council's position on 23 September. This demonstrates that that the technical inconsistencies that emerged during the council session on 19 June[2] have been dealt with, the council said. It added that after translation of the English text into the other 23 official EU languages, the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) will approve the texts on 5 October.

The council's view of the texts is that there have been no major changes since the June meeting, and "nothing on the big political issues". It is likely that the reprocessing of single-use devices (SUDs) and additional regulatory steps for high-risk devices will become important subjects in the MDR side of the discussion as the trilogues commence.

On the IVDR side, industry will be keen to ensure that diagnostics issues do not get overshadowed by these ostensibly weightier themes in the MDR. IVD manufacturers will be pushing for diagnostics-industry relevance, wary that some pieces of the IVDR proposal might simply have been lifted from the MDR. Others will be keen to fix a proper definition of a companion diagnostic, rather than a loose one that could apply to almost any IVD.

The proposed council texts and annexes can be accessed here. Some of the key changes signalled by the council compared with the commission's proposals on the MDR are in the areas of:

- reprocessing and further use of SUDs – this may only take place where permitted by national law, and in respect of the requirements laid down in the MDR. Member states may decide that the reprocessing and re-use of SUDs within a health institution may vary from the obligations of the manufacturer described in the MDR. Appropriate national regulations should exist. Reprocessing should ensure at least the same level of security as in the case of the corresponding initial SUDs. This also applies if the reprocessing is carried out by an external reprocessor on behalf of a health institution;
- Eudamed (the medical device database) – to facilitate the functioning of Eudamed, a medical device nomenclature should be available free of charge to manufacturers and other natural or legal persons obliged to use that nomenclature under this Regulation. Furthermore this

nomenclature should be provided, to the maximum possible extent free of charge, also to other stakeholders;

- notified bodies – EU member states may lay down additional requirements on notified bodies designated for conformity assessment of devices based on their territory as concerns issues that are not regulated in the MDR;
- high-risk devices – for Class III implantable medical devices, the authorities should be informed about devices which are subject to conformity assessment, and expert panels should be requested to scrutinize the preliminary assessment conducted by notified bodies on clinical data… this clinical evaluation consultation should lead to a harmonized evaluation of high-risk medical devices by sharing expertise on clinical aspects on categories of devices that have undergone this consultation process; and

The council proposals also allow for Class III device manufacturers to consult voluntarily expert panels on their clinical development strategy and proposals for clinical investigations. The council deletes a commission wording that recommended that Class III devices require explicit prior approval of their design and manufacture before they can be placed on the market.

These are just some of the main issues that the council has highlighted, and will doubtless be hotly debated as of 13 October.

References

1. Council of the European Union press release, Sept. 23, 2015, www.consilium.europa.eu/en/press/press-releases/2015/09/23-medical-devices/
2. EU medtech reform makes landmark move,

Source: *Ashley Yeo* , Scrip Regulatory

8. About us:

By L. Wenzel

P.SS.T is primarily specialized in the area of Medical Devices and new drug development, beginning with licensing and subsequent planning of pre- and clinical development phases and the respective project management up to marketing authorization applications and pre-marketing activities. Monitoring of clinical studies is as well included in our own services. Additionally we offer resources from our co-operation partners worldwide. We provide scientific services for all sections of healthcare, medicine, medical devise, cosmetics and pharmaceutical industry.

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