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European Regulatory Roundup, June 2021: Medtech Goes Into Document & Decision Overdrive

by Amanda Maxwell

Keeping up with the huge volume of work coming out from European bodies intended to support the implementation of the Medical Device and IVD Regulations is industry's latest challenge.

Although the Medical Device Regulation is now fully applicable, June saw an explosion of documents from the European bodies active in shaping the implementation of the new medtech regulations, as well as some critical documents shaping the future implementation of the IVD Regulation and key decision-making.

The Medical Device Coordination Group (MDCG), the group supporting the commission in the implementation of the new medtech regulations, has been particularly active and has endorsed four key guidance documents made public during the June:

MDCG 2021-10	***How Compliance With International UDI Rules Can Help Under New EU Rules***	A document intended to help those companies already compliant with the N48 IMDRF UDI guidance make the transition to EU requirements, as well as vice-versa. It endorses key IMDRF principles and terminology.
MDCG 2021-11	***How To Distinguish The 'Device Type' For Implant Card Purposes In The***	A total of 88 different types of implantable devices feature on a listing of device types published by the MDCG to help manufacturers determine the type of information they should provide on an implant card.

	EU	
MDCG 2021-12	***How The EU's Device Nomenclature Operates: Free Of Charge And Accessible To All***	The five-page text explains how the EMDN supports the functioning of the European database on medical devices (Eudamed).
MDCG 2021-13	***How Firms Withdrawing 'Old' Products Or Producing Legacy Products Must Comply With MDR***	This document advises how manufacturers of only legacy products or only "old" products, as well as of custom-made devices and producers of system and procedure packs, should register in the new version of Eudamed. The MDCG document makes it clear that if products are still made available on the EU market or still in use, their manufacturers will have to register as actors.

MDCG Also Endorses IVDR Super Plan

One particular highlight of the month was the European Commission publishing a joint implementation and preparedness plan for the IVD Regulation to tackle its "significant" and "serious" challenges.

The plan, endorsed by the EC's Medical Device Coordination Group (MDCG), lays out priorities for member states and commission services to ensure an operational system is in place before the IVDR date of application on 26 May 2022.

The main aim of this plan, the MDCG notes, is to agree "where to focus limited resources in the shorter term to ensure delivery as soon as possible and by the date of application."

Commission's Eudamed Implementing Regulation Draft

The European Commission, meanwhile, also published a *draft Implementing Regulation* laying down rules around how the Eudamed medical device database will work in practice.

Many of these rules are focused on dealing with potential problems that could arise, including malfunction of the database and fraudulent activity. The document also discusses planned tools are for actor training and practice so data will be submitted successfully from the beginning.

Market Surveillance Initiative Launch

In addition to the MDCG and Commission producing vast amounts of guidance in June, the Competent Authority for Medical Devices (CAMD) group, which brings together competent authorities in shaping priorities and implementation plans, *gave a progress update on the readiness of the EU's new market surveillance system.*

This is a second strand to the initiative that was unleashed nearly a decade ago in response to the PIP breast implant scandal; the first was the tightening up of oversight of and activities carried out by notified bodies and included the reinforcement of requirements for unannounced audits.

While a two-year pilot phase of the Joint Inspection Group's activities was launched last year, joint manufacturer inspections have not yet been conducted due to the pandemic. But virtual training sessions have been organized for all inspectors across Europe.

CAMD And EMA Collaborate

CAMD also spent time in June discussing *future coordination with the European Medicines Agency* concerning drug/device borderline and combination products in the context of the new MDR and IVDR. The aim is to create a structured dialog. Meeting outcomes have yet to be released.

Latest Notified Body Appointment

In other news, Netherlands' DEKRA was appointed the *fifth notified body under the IVDR*.

Meeting Highlights

The Informa Connect EU MDR Exchange meeting in mid-June provided an opportunity for companies with experience of applying the MDR requirements to their products to talk about *some of the challenges they encountered as they worked through the audit process with notified bodies*.

It was also during this event that Paul Piscoi, policy officer in the commission's medical devices unit, said that the European Commission only expects 10-20% of files sent by notified bodies for expert panel review will actually need an expert panel opinion.

Expert panels are required to review notified body clinical evaluation work for certain high-risk medical devices, namely class III implantable devices and class IIb active devices that are intended to administer and/or remove a medicinal product, as well as for some class D IVDs under the IVDR.

The recently established expert panels, he said, have only received two files so far in the context of the MDR. An opinion on one of these files is imminent.

Also during June, the Council of the EU agreed a proposal that foresees the EMA providing the structure for the functioning of the expert panels.

The news comes as EU member states adopted a common position on a proposed regulation to strengthen the EMA role in crisis preparation and management, not just in the area of medicines but also in that of medical devices.

- For last month's regulatory roundup, see: *European Regulatory Roundup, May 2021: MDR Becomes Only Regulatory Option Amidst Concerns*

Rank	Title
1	***European Commission's Eudamed Draft Implementing Regulation Tackles Problems Head On***
2	***How Firms Withdrawing 'Old' Products Or Producing Legacy Products Must Comply With MDR***
3	***European Regulatory Roundup, May 2021: MDR Becomes Only Regulatory Option Amidst Concerns***
4	***How The EU's Device Nomenclature Operates: Free Of Charge And Accessible To All***
5	***How Compliance With International UDI Rules Can Help Under New EU Rules***
6	***Commission's eIFU Draft Unleashes Diametrically Opposed Views Among Device Users***
7	***EU's IVDR Plan Demands Team Effort And Flexibility From All Stakeholders***
8	***MDR Practicalities: Companies Explain Impact Of Notified Body Timings And Questions Process***
9	***EU Coordinates Market Surveillance For The First Time: Pilot Being Launched***
10	***Good News For Medtech Regulation In The EU As Turkxit Is Avoided***