MEDTECH INSIGHT
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2017: Year Of The New EU Medtech Regulations: But Is EU Ready?

by Amanda Maxwell

2017 is going to be a pivotal year for EU medtech regulations. We are expecting the new Medical Devices Regulation and IVD Regulation to take effect. But there are some big concerns and uncertainties at the center of it all.

More than four years after the European Commission first published the current proposal for new medtech regulations in 2012, 2017 looks set, at last, to be the year the EU's Medical Devices and IVD Regulations are adopted and enter into force.

Adoption will likely take place in March, and then the regulations will enter into force on the 20th day after their publication in the Official Journal of the European Union, which is currently expected in May.

The stage seems to be set for new, much tougher EU medtech regulations – as long as there are no more hurdles to overcome.

The latest indications are that there have been some recent changes made to the texts since they were first publicly released last year. Certainly, the Medical Devices Regulation is reported to have grown by 15 pages to some 370 pages, compared with the version agreed by the Council, Commission and Parliament in June 2016.

But there has been no suggestion yet that there are any far-reaching changes in the latest texts, and there is hope they the additions will include clarifications, in particular, about what happens during the three- and five-year transition phases for MDR and IVDR, respectively. Will notified bodies still be able to audit against the Medical Devices Directive (MDD) in that phase? And for how long will compliance with the current requirements of the MDD suffice?

Much Uncertainty

Even after the new texts have been adopted and have entered into force, it is still far from the end of the story.

With some 80 delegated and implementing acts to draft (many of which are mandatory - (Also see "*Brexit: The UK MHRA's View Of The Elephant In The Room*" - In Vivo, 16 Dec, 2016.), industry will be far from seeing the full picture of what it needs to do to ensure compliance when the regulations first take effect, scheduled for later this year.

Other issues that are causing a huge degree of concern include:

- How soon the new version of Eudamed, the EU medical device database underpinning the entire regulatory structure, will be available and how delays could impact implementation and compliance.
- The political future of the EU, including the impact of Brexit, on the EU regulatory picture.
- The time it will take to re-designate all notified bodies under the new regulations.
- The notified bodies' ability to survive in the considerably tougher regulatory environment including the growing capacity issues that are coming at their busiest time in EU medtech regulatory history.
- How the various actors in the sector – the authorities, the notified bodies and companies – are going to manage in an environment characterized by huge demands for change but inadequate resources.
- New demands on existing products before and after the medtech regulations take effect and are fully applied.

What Hit The Headlines?

During 2016, the issues surrounding notified bodies, their responsibilities and their capacity hit Medtech Insight's headlines again and again. Indeed, notified bodies featured in the titles of six out of our top 20 EU regulatory headlines last year.

All eyes were on progress towards the Council of the European Union, the European Parliament and the European Commission reaching political agreement on the texts during the first half of the year, taking it a step closer to final adoption.

Then, since the publication in June of these near-final versions of the texts, there has been a scramble to understand what the real impact of the changes.

Our Regulatory Recap stories which, so far, have looked at the first five of the 10 chapters in both the MDR and IVDR, have been among the most popular EU regulatory articles. Regulatory Recap

pieces accounted for four of the top 10 EU regulatory Medtech Insight pieces, with the introductory piece to this series, *The New EU Regulations, A Guide To The Texts*, hitting the number one spot.

Brexit And Clinical Evaluations

There has also been a very keen interest among readers to understand the implications of Brexit and what it will mean for future trade between the UK and Europe, including the regulatory fall-out.

Among the main concerns are what will happen to UK notified bodies and authorized representatives? This is a key question – UK notified bodies are understood to account for some 50% of the testing of high-risk medical devices in the EU, and authorized representatives to number around 1,000 in the UK and represent 50% of the EU's stable of these organizations.

Clinical evaluation has been another issue that has drawn high numbers of readers – companies are finding that notified bodies are already auditing against much tougher requirements and are questioning whether this is necessary now as it creating huge and expensive hurdles for many of them.

During 2017, *Medtech Insight* will continue to scrutinize the implications of the political decision-making, and watch closely as the new texts are adopted and published to see what changes and clarifications may appear. There is no doubt that notified bodies, clinical evaluation, what happens during the transition period that is looming up now, and the status of products with a proven safety record under the current directives will continue to dominate our headline news.

The following table lists the top 20 EU medtech regulatory headlines in 2016 for *Medtech Insight*:

Rank	Story Title	Month
1	*The New EU Regulations: A Guide To The Texts*	July
2	*Regulation Recap: A Look At Scope And Definitions In New EU Rules*	August
3	*Companies Fear EU Clinical Evaluation Guidance Document Is Becoming De Facto Law*	October
4	*EU Regulation Recap: Economic Operators, Reprocessing, CE Marking And Free Movement*	August
5	*Notified Body Numbers Continue To Fall*	October
6	*Brexit Q&A: Where Do Notified Body, Authorized Representative Offices Need To Be?*	October
7	*EU Regulation Recap: Guides For Finding Your Way Around The New Texts*	September
8	*EU Regulation Recap: Traceability and UDI, Registration, Eudamed, And More From MDR/IVDR Chapter III*	August

9	*Europe Readies For Big Changes In Device Postmarket Surveillance*	February
10	*Crack Open The Champagne! EU Reaches Agreement on Future Medtech Regulations*	May
11	*Notified Bodies, Authorized Reps And The CE Mark How Does Post Brexit Uncertainty Cloud Future MDR*	June
12	*More EU Clinical Data Requirements Coming With New Regulations*	September
13	*Notified Bodies Can Concurrently Audit Under New And Old EU Rules, UK Official Confirms*	November
14	*"No More Questions" On Scrutiny As EU Talks Set To Give Notified Bodies Yet More Responsibility*	March
15	*EU Regulation Implementation Deadlines And Other Pressing Issues*	October
16	*When Will Medtech Actually Have To Comply With New EU Regs? This May Surprise You*	April
17	*Market Surveillance In The EU The Next Big Wave of Change Approaches*	January
18	*New EU Regulations: What Could Possibly Go Wrong?*	November
19	*Notified Body Preparations For New Regulations Reveal Some Horror Stories*	December
20	*Brexit: Questions That Arise As Regulators Fumble In The Dark*	August

From the editors of Clinica