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Focus - From an industry partner to an industry enforcer: How is the strengthened role of Notified Bodies under the new EU Regulations affecting companies?

Notified Bodies (NBs) are the entities responsible for assessing and granting certificates for the majority of medical devices and *in vitro* diagnostics placed and distributed in the European market and beyond. The new Medical Device Regulation (EU) 2017/745 and the *In Vitro* Diagnostic Regulation (EU) 2017/746 impose burdensome obligations impacting both NBs and a significant number of devices. Given the current status of the designation process, there is general scepticism about the availability and capacity of NBs to meet industry's demands by the deadlines imposed by the new Regulations. Stakeholders are discussing the possibility of postponing the date of applications of both Regulations. On the one hand, the facts do seem to support such a proposal, but on the other hand, it seems very unlikely that Parliament and the Council will re-start the revision process of the texts and a reopening of the legislative procedure. This article examines the requirements that must be met by NBs to obtain designation, the current status of NB designation applications under the Regulations, how industry should prepare for the changes ahead, and what manufacturers should do if their NB ceases activities. More >>

Focus - 510(k)s: Deciding when to submit a 510(k) for a change to an existing device

Medical devices are modified for numerous reasons as part of the innovation process as well as to address changes in technology. For medical devices cleared via the US Food and Drug Administration's (FDA's) pre-market notification (510(k)) process, review of all changes to determine when to submit a new 510(k) is a critical task. Recently, the FDA updated its guidance entitled, *Deciding When to Submit a 510(k) for a Change to an Existing Device*. As a result of the growing use of software in devices, the Agency also issued a separate guidance focused on software changes entitled, *Deciding When to Submit a 510(k) for a Software Change to an Existing Device*. Both guidance documents provide detailed discussions to help manufacturers evaluate changes and provide numerous examples to illustrate the various decision points. This article outlines the basic principles and discusses some specific illustrative examples. More >>

Focus - Clinical evidence: Current challenges for manufacturers implementing Regulation (EU) 2017/745

With the introduction of the Medical Device Regulation (EU) 2017/745 (MDR) in May 2017, the safety, performance, and clinical benefit of medical devices became key requirements for compliance. Manufacturers are obligated to provide evidence for these crucial issues. Health protection for patients and users is the primary objective. To achieve this, clinical evidence, which is based on clinical data and clinical evaluation results pertaining to the specific device, is mandatory. But what are clinical data? Taking a look at the medical device industry, it is obvious that manufacturers have a variable understanding of the term – especially regarding the relevance of such data in the context of the requirements defined in the Regulation. An awareness of the importance of this topic exists to some extent, but clinical data have been rather neglected so far. This article focuses on the definition of clinical evidence, its role in certification, and the related impact for manufacturers. A detailed overview of different kinds of pre-clinical data is given as well as how to use these data for market entry. Further critical factors like the state-of-the-art and medical alternatives, as demanded by MEDDEV 2.7/1 revision 4, are discussed. Another requirement that needs to be kept in mind is the differentiation between technical and clinical claims and the need to prove clinical claims with respective clinical data. This article looks at real-life experiences, related problems, and potential solutions for manufacturers that are associated with the application of the MDR in May 2020. More >>

Focus - Product Liability Directive: Is it good enough for emerging technology?

The Product Liability Directive 85/374/EEC sets out the liability for defective products in the European Union (EU). It is reviewed every five years, with the Commission producing a report that takes into consideration the efficacy of the legislation, its application in any significant case law, and whether any amendments are necessary. This article reviews the 2018 report, which has focused on how Directive 85/374/EEC has been applied to new technologies, including non-embedded software, robotics, artificial intelligence, complex applications (apps) and so forth, and asks whether the Directive is fit for purpose. More >>

Country Overview - Zimbabwe

The Medicines Control Authority of Zimbabwe has provided an overview of the medical device regulatory requirements that exist in Zimbabwe in both draft and final form. The legislative framework is summarised, with more details on database listing, import/export controls, the sale of medical devices, advertising, and fees. Contact details for the regulatory authority are also given. More >>

European News

- **EU**: UDI guidance documents developed by the MDCG to support implementation of MDR
- **EU**: Basic guidance issued for manufacturers on implementation of the MDR and IVDR
- **EU**: Public rolling plan for implementation of new EU Regulations

- **EU**: Proposed updates to Common Technical Specifications for certain IVDs, especially HIV and HCV tests
- **France**: Control of presentation, information or promotion for health products extended to certain medical devices
- **Serbia**: Clarification on payment of annual vigilance fees for medical devices
- **Serbia**: New regulations published that affect medical devices
- **UK**: MHRA fees unchanged for 2018/2019
- **UK**: Guidance released on products without an intended medical purpose under Regulation (EU) 2017/745

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North American News

- **Canada**: Changes to evidence requirements for Class II and Class III infusion pumps
- **Canada**: Applications for medical device Investigational Testing Authorisations (ITAs)
- **Canada**: Use of Regulatory Enrolment Process using the Common Electronic Submission Gateway to be piloted for medical devices; ToC format to be adopted
- **Canada**: Pilot project to formalise a framework for offering regulatory advice to device manufacturers to be launched
- **Canada**: Guidance on 3D printed devices in development
- **Canada**: Proposed changes to the List of Recognised Standards for medical devices
- **USA**: FDA medical device user fees for Fiscal Year 2019
- **USA**: Voluntary Malfunction Summary Reporting Program to streamline malfunction reporting for certain devices
- **USA**: GUDID submission deadline extended for device constituents of co-packaged combination products assigned to CDER
- **USA**: Reclassification of single-use female condom and renaming as single-use internal condom
- **USA**: Haemostatic device for intraluminal gastrointestinal use classified into Class II
- **USA**: Herpes virus nucleic acid-based cutaneous and mucocutaneous lesion panel classified into Class II
- **USA**: Class II classification for the positive airway pressure delivery system
- **USA**: Intranasal electrostimulation devices for dry eye symptoms classified into Class II (special controls)
- **USA**: Class II classification for the thermal vestibular stimulator for headache
- **USA**: External upper limb tremor stimulator becomes Class II (special controls)
- **USA**: Class II classification for the light based energy source device for topical application
- **USA**: Class I classification for the wound autofluorescence imaging device
- **USA**: Proposed reclassification of ultrasound cyclodestructive devices
- **USA**: Proposed list of accessories suitable for classification into Class I
- **USA**: Paper/multiple copies of submissions could be replaced by electronic submissions
- **USA**: Recommendations for labelling and safety testing of heparin-containing medical devices and combination products
- **USA**: Benefit-risk factors to consider when determining substantial equivalence in 510(k) devices with different technological characteristics
- **USA**: Guidance on appropriate use of voluntary consensus standards in pre-market submissions for medical devices
- **USA**: Draft guidance on content of pre-market submissions for management of cybersecurity in medical devices
- **USA**: Recognition and withdrawal of voluntary consensus standards addressed in draft guidance
- **USA**: Eliminating routine FDA re-review of third party 510(k) reviews: formal plan and draft guidance
- **USA**: Pilot programme to improve 510(k) review process for OCT devices
- **USA**: Guidance on consideration of uncertainty in benefit-risk determinations for certain pre-market submissions
- **USA**: Proposed expansion of the Special 510(k) Program
- **USA**: Process for persons denied a Certificate to Foreign Government for a device is clarified in draft guidance
- **USA**: Pre-market submission recommendations drafted for peripheral vascular atherectomy devices
- **USA**: Comment period reopened for draft guidances on coronary drug-eluting stents
- **USA**: CDRH publishes proposed guidance development lists for fiscal year 2019
- **USA**: Modifications to the list of US FDA-recognised standards

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Central & South American News

- **Brazil**: Requirements drafted for custom-made and patient-specific medical devices
- **Brazil**: Procedure for handling imported medical devices with different terms of validity
- **Chile**: Natural rubber latex male condoms, male synthetic condoms and female condoms to be incorporated into health control system
- **Peru**: New definition for a medical device manufacturer

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Asia, Africa & Middle East News

- **AHWP**: Guidance on labelling for in vitro diagnostic medical devices
- **Australia**: Application fee change for export only medical devices
- **Australia**: Updated requirements specified for preliminary assessment of applications for inclusion in the ARTG
- **Australia**: TGA to make greater use of overseas marketing approvals
- **Australia**: Certificates of Free Sale and Export Certificates
- **Australia**: Comments solicited on proposed regulation of IVD companion diagnostics
- **Australia**: Guidance issued on electronic IFU for professional users of medical devices
- **China**: Regulation drafted to control Chinese agents of imported medical devices
- **Egypt**: Use of ES 1595-1 on single-use, sterile rubber surgical gloves is now mandatory
- **Hong Kong**: Web-based IVD classification programme developed by MDCO
- **India**: Comprehensive reference document on device regulations prepared by IPC
- **Israel**: Two Parts of SI 1268 on syringes and needles are proposed for revision
- **Korea (Republic of)**: Adoption of ISO 13485:2016 proposed
- **Malaysia**: Transition period for meeting medical device labelling requirements extended by three years
- **Malaysia**: Registration exemption for export only medical devices
- **Malaysia**: Rule for devices imported from/exported to countries without diplomatic ties with Malaysia
- **Malaysia**: Borderline and combination product classification examples
- **Saudi Arabia**: 'Guidance for the Medical Devices Samples for Laboratory Testing'
- **Singapore**: Regulatory fees for medical devices to increase from 2 April 2019
- **Uganda**: Draft standard on sterile surgical blades

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