

What's new in Medical Device Regulation

Dr Haidong Liang, PhD

Clifton Medtech Consulting

info@cliftonMedTech.com

<http://cliftonmedtech.com/>

What is the issue?

- Existing EU Directives – dating back to the 1990s
 - have not kept pace with the enormous technological progress in the past 20 years.
- EU countries interpret and implement the current rules differently
- Not always possible to trace medical devices back to their supplier
 - new rules on traceability are needed.
- Patients, healthcare professionals and others do not have access to
 - essential information on assessment on medical devices
 - clinical evidence to show they are safe and effective.
- Need for greater transparency is highlighted by recent scandals
 - faulty silicone breast implants
 - problems with some metal-on-metal hip replacements.

Who will benefit and how?

- Patients and citizens
 - all medical devices will have to undergo thorough, independent assessment of safety and performance before they can be sold on the European market.
 - controls will not block or unduly delay access to innovative, cost-effective devices
- Healthcare professionals
 - better information on the benefits for patients, residual risks and the overall risk/benefit ratio
 - make the best use of medical equipment.
- Manufacturers
 - clearer rules, easier trading between EU countries and a level playing field,
 - with penalties for those who don't play by the rules.
 - new rules support patient-oriented innovation
 - take particular account of the specific needs of the many small and medium sized manufacturers in this sector.

What will change?

- Wider, clearer scope for EU legislation on medical devices
 - extended to include, for example, implants for aesthetic purposes, and clarified as regards to genetic tests
- Stronger supervision of independent assessment bodies by national authorities
- More powers for assessment bodies
 - ensure thorough testing and regular checks on manufacturers, including unannounced factory inspections
- Clearer rights & responsibilities for manufacturers, importers and distributors,
 - apply to diagnostic services and internet sales
- Extended Eudamed database on medical devices
 - provide comprehensive information on products available on the EU market
 - Non-confidential data will be publicly available

What will change?

- Better traceability of MD throughout the supply chain
 - enabling a swift and effective response to safety problems (e.g. recalls)
- Stricter requirements for clinical evidence to support assessments of MD
- Updated classification rules
 - New labelling rules
 - keep pace with technological and scientific progress
- Better coordination between national surveillance authorities
 - Commission provide scientific, technical & logistic support
- International guidelines to be incorporated into EU law.

European Commission Expectation

- Increased patient safety
- Scope of legislation
- Governance of system and transparency
- Criteria for designation, monitoring and obligations of notified bodies
- Risk classification of devices and the safety and performance requirements
- Obligations of economic operators
- Clinical evaluation, traceability and reprocessing of single-use devices

Wider and clearer scope of EU legislation

- MDR scope is expanded to include new product lines
 - Annex XV, devices and their accessories as well as some accessories to sterilized products will have to comply with MDR requirements.
- Inclusion of devices without a medical purpose
 - aesthetic products which present the same characteristics and risk profile as analogous MD
 - implants devices and materials for aesthetic purpose
 - coloured contact lenses
 - devices designed for the purpose of “prediction” of a disease or other health condition.

Improved transparency

- Establishment of a comprehensive EU database on medical devices
 - Extended database on medical devices (Eudamed) providing comprehensive and public information on products available on the EU market
 - collecting all relevant information
 - covering economic operators, Notified Bodies
 - market surveillance vigilance, clinical investigations, certificates and product information
- A Unique Device Identification (UDI) system will be required for labeling
 - better traceability of devices throughout the supply chain to final user
 - enabling a swift and effective response to safety concerns (e.g. recalls);
- The introduction of an EU-wide requirement for an 'implant card'
 - to be provided to patients containing information about implanted medical devices
- More transparency for patients and increased traceability

Classification

- Spinal implants, devices that control and monitor active implants, nanomaterials, aphoresis machines, and combination products
 - will be reclassified as Class III devices requiring technical documentation known as a design dossier.
 - require a design examination certificate.
 - product-specific CE Certificates require review and approval of all design changes, whereas under the current system, only significant changes require review and approval.

Vigilance

- Improved coordination between Member States in the fields of vigilance and market surveillance.
- Rigorous post-market oversight
 - grant Notified Bodies increased post-market surveillance authority.
 - unannounced audits, along with product sample checks and product testing
 - strengthen the EU's enforcement regime and help to reduce risks from unsafe devices.
 - annual safety and performance reporting by device manufacturers will also be required in many cases.

Clinical data

- Reinforce rules on clinical data
 - EU-wide coordinated procedure for the authorisation of multi-centre clinical studies on devices
- Reinforce requirement for manufacturers to collect data about post market use of their devices
- Manufacturers may rely on equivalent products **only under very strict conditions**
 - manufacturers may only use data **from clinical investigations**
 - **stricter rules for conducting clinical investigations**
 - evidence of safety and performance proportionate with risk associated with a given device.
- Strengthen protection for patients who take part in clinical investigations
- Improve the availability and accessibility of clinical data of these devices
- Provide criteria for, and restrictions on, clinical investigations, and allows for individual member states to further restrict certain practices within the scope of a clinical investigation.

Formatting of technical files

- Manufacturers will be required to update
 - the format of technical files
 - declarations of conformity, and labeling.
- create a summary document for each section instead of providing complete protocols and reports

Change re Manufacturers

- Face increased post market surveillance requirements.
- Form a post market surveillance system "proportionate to the risk class and appropriate for the type of device"
- Submit periodic safety update reports on an annual basis
- Act faster in response to serious public health threats or deaths caused by devices
- Demonstrate that their products have an acceptable benefit to risk ratio.
- Disclose more clearly any residual risks associated with a device.
- For high-risk devices, must conduct clinical investigations to demonstrate their product's safety and performance.
- Provision to allow manufacturers of class III (highest risk) devices to consult with an expert panel to provide feedback on the company's clinical investigation strategy

Change re manufacturers

- All medical device manufacturers selling in Europe will need to establish
 - risk management systems (art. 8.1a)
 - quality management systems (art. 8.5)
 - manufacturers of Class I self-certified devices are exempt from being required to have their quality management systems assessed by a Notified Body (art. 42.5).
- "Own Brand Labeler (OBL)" manufacturers will practically be made history
 - All OBL devices will need to have full Technical Files (art. 8.2, art. 8.4), as well as clinical data (art. 8.2).
- Tighter control over distribution chains
 - Requirements for importers, distributors and Authorized Representatives are brought in line with New Legislative Framework requirements listed in Decision 768/2008/EC;
 - new requirements for importers and Authorized Representatives are also introduced.
- Clearer rights and responsibilities for manufacturers, authorised representatives, importers and distributors, including in the case of diagnostic services and internet sales;
- Identification of “qualified person”
 - Device manufacturers will be required to identify at least one person within their organisation who is ultimately responsible for all aspects of compliance with the requirements of the new MDR. The organisation must document the specific qualifications of this individual relative to the required tasks.

Authorized Representatives liability

- liability increases
 - AR will be held jointly and severally liable for defective medical devices,
 - prompting these organizations to scrutinize non-EU based manufacturers more carefully before accepting their business;
 - AR will more thoroughly and frequently monitor such clients' compliance, and seek insurance policies to cover added residual risks.

MDCG

- Medical Device Coordination Group
 - composed of members representing national competent authorities in the field of medical devices
 - ensure better coordination between Member States, with the Commission providing the necessary scientific, technical and logistic support.

New role of notified bodies

- Changed role for Notified Bodies
 - these entities' roles will change from "industry partners" to "policing bodies."
- More stringent rules for Competent Authorities and the Notified Bodies they monitor
- Stronger supervision of independent conformity assessment bodies (NB) by national authorities;
- More powers for notified bodies vis-à-vis the manufacturers
 - ensure thorough testing and regular checks
 - unannounced factory inspections at manufacturing sites;
- Only newly created Special Notified Bodies will be able to issue CE Certificates for high-risk devices such as implants.

Common Technical Specification (CTS)

- EC's ability to create common technical specifications (CTS) will be expanded to all devices.
- EC or expert panels to be defined to publish Common Specifications which shall then be taken into account by manufacturers as well as Notified Bodies.
- Common Specifications shall exist in parallel to the Harmonized Standards and the State of the Art.
- CTS may be written where no Harmonised Standards exist to address General safety and performance requirements
- Devices which are in conformity with the CTS shall be presumed to be in conformity with the requirements of the Regulation
- Manufacturers shall comply with the CTS unless they can duly justify
 - they have adopted solutions ensuring a level of safety and
 - performance that is at least equivalent

High risk devices

- Strengthened rules for high risk devices
- An additional check by experts (e.g. panels and laboratories) for high risk devices such as implants, prior to placing them on the market
- stricter pre-market control of high-risk devices with the involvement of a pool of experts at EU level

Overall impact

- Safer medical devices
- CE Marking process could also become more expensive and slower
- New regulations are likely to result in much higher costs with minimal benefit for manufacturers.