Update: Proposed Medical Device Regulation (MDR) & IVD Regulation (IVDR)

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Disclaimer

• The new regulations are not finalized and subject to change

European Commission Proposal September 2013

• After public consultation
• Build on strengths
  • Balance between pre- and post-market control
  • Flexible – Supportive of innovation
  • High safety levels
  • Raid access to market – Cost-effective and SME friendly
• ...but adapt and improve
European Commission Expectation

• Towards 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, including reprocessing of single use devices
  • Clinical evaluation, traceability and reprocessing of single-use devices
European Commission – Response to PIP

• Lesson learned from PIP scandal
• Amendments from ‘stress test’
  • Reinforced control of high-risk devices through a scrutiny mechanism
  • Obligation for manufacturers to provide an implant card
  • Qualified person responsible for regulatory compliance
  • Notified bodies to conduct unannounced visits, carry-out physical or laboratory tests and rotate auditors
• Member States to encourage incident reporting by healthcare professionals and patients
Three Directives become Two Regulations

• Direct entry into force
  • Three year transition period for MDD/AIMD
  • Three or five year transition period for IVD*

• Regulation should result in more consistent application

*Parliament proposed three year transition for IVDR / industry lobbying for five year
1. Proposal from Commission
2. First reading by EP position
3. Amended proposal from Commission
4. First reading by Council
5. Council approves all EP's amendments
6. Council can adopt act as amended (without further amendments and in the wording of EP's position)
7. EP has approved proposal without amendments
8. Council can adopt act (without amendments and in the wording of EP's position)
9. Council position at first reading
10. Communication from Commission on Council position at first reading
11. Second reading by EP
12. EP approves common position or makes no comments
13. Act is deemed to be adopted
14. EP rejects Council position at first reading
15. Act is deemed not to be adopted
16. EP proposes amendments to Council position at first reading
17. Commission opinion on EP's amendments
18. Second reading by Council
19. Council approves amended Council position at first reading
   (i) by a qualified majority if the Commission has delivered positive opinion
   (ii) unanimously if the Commission has delivered negative opinion
20. Act adopted as amended
21. Council does not approve the amendments to the Council position at first reading
22. Conciliation Committee is convened
23. Conciliation procedure
24. Conciliation Committee agrees on a joint text
25. EP and Council adopt act concerned in accordance with joint text
26. Act is adopted
27. EP and Council do not approve joint text
28. Act is not adopted
29. Conciliation Committee does not agree on joint text
30. Act is not adopted
Timelines – Council discussions ongoing – Trilogue asap

| Year | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 |
|------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| 2013 |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 2014 |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 2015 |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 2016 |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 2017 |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 2018 |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 2019 |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 2020 |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 2021 |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |

European Parliament 1st Reading – October 2013
Finalise 1st or 2nd Reading – Q4 2014 / Q1 2015

Designation of Notified Bodies
3 Year Transition
3 Year Transition*

Regulation covering MD & AIMD
Regulation covering IVD

*IVDR – Possibly 3 or 5 year transition
Delegated Entities under the Proposed Regulation

- European Commission (EC)
- EU Member States (MS)
- EU Competent Authorities (CA)
- Medical Device Coordination Group (MDCG)
- Medical Device Advisory Committee (MDAC)
- Assessment Committee for Medical Devices (ACMD)
- EU Reference Laboratories (EURL)
- European Medicines Agency (EMA)*
- Notified Bodies (NB)
- Special Notified Bodies (SNB)*

*EC – Need to carefully assess the added value of the EMA involvement
Designation of Notified Bodies & Special NBs

- **Notified Body**
  - MDR Class IIa/IIb**
  - IVDR Class B/C

- **Special Notified Body**
  - MDR Class III/IIb**
  - IVDR Class D

*Class I non-sterile / non-measuring

**Under MDR Special NB needed for higher risk devices: class III, implantable, devices intended to administer medicinal products
<table>
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<th>Where 'M' is date in force</th>
<th>Prior to 2015 'M'</th>
<th>2015 'M' to 2018 'M'</th>
<th>2018 'M'</th>
<th>2020 'M'</th>
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<td>Valid Until Expiration Date</td>
<td>Valid Until Expiration Date</td>
<td>Must Expire Prior to 2020 'M'</td>
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<td>Issued Before 2015 'M'</td>
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<td>CE MDR Certificates</td>
<td>Issued by MDR NB up to 5 Years &amp; Renewable</td>
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Single-Use Devices

• Single-use device – ‘...has been tested and demonstrated impossible to reuse.’
• Devices labeled as single-use should really be single-use
• All devices should be reusable as a rule, unless they are on a list established by the EC after consultation with MDAC
• Reusable device – ‘...suitable for reprocessing’ for multiple patients/procedures
• Diverging views between Member States
• EC proposal balanced approach
Economic Operators

Economic operators means the manufacturer, the authorised representative, the importer and the distributor

Manufacturer
means the natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under his name or trademark

Importer
means any natural or legal person established within the Union who places a device from a third country on the Union market

Distributor
means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a device available on the market
Increased Control of the Supply Chain

Manufacturer

Crucial Suppliers
OEM’s
Sub contractors

Distributers
Importers
Authorised Representatives
General Obligations of Manufacturer

- Design and manufacture devices in accordance with the regulation
- Draw up required technical documentation
- Complete an appropriate conformity assessment
- Prepare a declaration of conformity
- Make technical documentation available to CA's (STED)
- Operate a quality management system and maintain product conformity
- Conduct post market surveillance
- Supply adequate instructions for use in a MS language
- Procedures for devices that do not comply – including vigilance
- Identify suppliers conducting device design, manufacture
- Liability insurance
Obligations of Authorized Representative, Importers, Distributors

- Manufacturer designates by written mandate a single authorized representative confirmed in writing by the authorized representative
  - Prescriptive requirements for authorized representative
  - Written process for changing authorized representative
- General obligations of importers
  - Confirm: *manufacturer identifiable and competent, liability insurance, conformity assessment, authorized representative, technical documentation, devices CE Marked, labeled in accordance with regulation*
  - Identify themselves, registration, storage & transportation, records, complaints, non-conformity/corrective action responsibilities
Eudamed: European Electronic Database

- UDI
- Registration of devices and economic operators
- Information of certificates
- Clinical investigations
- Vigilance
- Market surveillance
- Public access
  - Allow comparison of devices, economic operators, clinical investigations, vigilance
Traceability in the Supply Chain

- For devices, other than devices for clinical investigation or performance evaluation, economic operators shall be able to identify the following, and will retain records for the 5 years after the last device has been place on the market:
  (a) any economic operator to whom they have supplied a device;
  (b) any economic operator who has supplied them with a device;
  (c) any health institution or healthcare professional to whom they have supplied a device.

Unique Device Identification (UDI)
- To facilitate traceability and recall devices will require a UDI
- Does not apply to devices for clinical investigation / performance evaluation
- The UDI will appear on the label
- Will need to be stored by the economic operators and the health institutions
- Approved systems will be designated by the Commission
  - Coherent if possible with a global regulatory approach to UDI
Person Responsible for Regulatory Compliance

- Manufacturers within their organisation at least one qualified person who possesses expert knowledge in the field of in vitro diagnostic or medical devices. This will include:
  - a degree or equivalent in natural sciences, medicine, pharmacy, engineering, law plus at least two years of professional experience in regulatory affairs or in QMS in medical devices or IVD’s or
  - **Three years** of professional experience in regulatory affairs or in QMS relating to medical devices or IVD’s

- Responsible for ensuring:
  - that the conformity of the devices is appropriately assessed before a batch is released
  - that the technical documentation and the declaration of conformity are drawn up and kept up-to-date
  - that vigilance requirements have been fulfilled
  - Subjects in clinical investigations or performance evaluation for interventional studies

- The qualified person should suffer no disadvantage by performing their duties
Classification Changes

• MDR classification changes
  • Brings AIMD and accessories are class III
  • Identifies spinal disk replacement implants and implantable devices that contact the spinal column are class III
  • Devices incorporating nanomaterial deliberately intended to be released to the human body are class III
  • Sutures and staples used in direct contact with CCS/CNS are not class III
Quantum Leap

**IVD Directive**

- Require a Notified Body
- Do not require a Notified Body
  - 80-90%

**IVD Regulation**

- Require a Notified Body
  - 80-90%
- Do not require a Notified Body
Declaration of Conformity

- Manufacturer name and address
- Statement that the manufacturer is taking responsibility for the device
- UDI device identifier
- Device identification – name, product code, catalog,
- Statement of compliance with the regulation
- Risk classification
- Harmonized standards used for conformity
- Notified body, conformity assessment, certificate
- Place, date of issue
- Name and function of signature, indication of who on behalf of signs
- Continuously updated and issued in one of the official EU languages
Safety and Clinical Performance Report

• For all class III and implantable device
• Based on data collected during the clinical investigation
• Submitted to Special Notified Body for review
• Special Notified Body will validate
• Must be understandable by users in the relevant local MS language
• The summary will be made available to the public through Eudamed
• Safety and clinical performance report shall be updated annually with clinical evaluation reports
Special Notified Body Assessment of High Risk Devices

- Only Special Notified Bodies shall conduct conformity assessment of high risk devices
  - MDR class III, implantable, class IIB intended to administer medicinal substance
  - IVDR class D
- Special Notified Bodies are designated by EMA
- All applications for high risk devices shall be notified to the EC
  - Notification will include:
    - Draft IFU
    - Draft summary of safety and clinical performance
    - Estimated date of completion of conformity assessment
  - Notification will be communicated to MDCG
  - Within 20 days MDCG may request prior to CE Marking SNB provide (Under IVDR triggered by three members of ACMD)
    - Clinical evaluation report (IVDR clinical evidence / clinical performance study)
    - Post Market Clinical Follow-up Plan
    - Information on marketing or not in third countries (results of evaluations)
Special Notified Body Assessment of High Risk Devices (continued)

- MDCG will consult ACMD
- At the latest of 60 days MDCG will issue opinion on documents submitted
  - Within that period <30 days ACMD may request additional information
- Within 15 days of receiving MDCG opinion SNB will indicate whether it agrees
- If SNB disagrees it has 30 days to submit further information and request re-examination
- MDCG in consultation with ACMD has a further 30 days to re-examine opinion
- Following unfavorable opinion SNB shall not issue a certificate
- SNB can submit new information and MDCG may reassess application
- Following unfavorable opinion manufacturer can request from EC a hearing to discuss the scientific grounds for the unfavorable scientific assessment
- The EC will make MDCG opinions available to the public
- The manufacturer will not be charged for the additional MDCG assessment
Parts and Components

• New requirement for suppliers of parts or components
  • Parts or components intended to replace parts or components that are defective or worn to maintain or re-establish performance of a device

• Responsibility to determine the part or component does not adversely affect the safety and performance of the device
  • Substantiating evidence available to CA’s
  • For implantable devices must cooperate with the manufacturer of the device

• Part or component that significantly changes the performance or safety characteristics of a device shall be considered a device in its own right.
Implant Card and Information about Implantable Devices

• Manufacturers of implantable devices shall provide implant card for particular patients
  • Implant card shall also be made available in an electronic format
  • Identifies device implanted including UDI
  • Warning, precautions, measures to be taken with reciprocal interference with external influences (e.g. compatibility with diagnostic devices)
  • Potential adverse effects
  • Information on expected life cycle and follow-up
  • Principal characteristics of device including materials
• Exempted implants: sutures, staples, dental implants, screws, plates
## Potential Certificate Transition from MDD to MDR

| EC MDR QA Certificate | • Upgrade QMS CA from MDD to MDR  
|                       | • Assess the gaps (additional requirements)  
|                       | • Sample technical files (IIa & IIb)  
|                       | • Issue MDR QA Cert  
|                       | • *MDD QA Cert may still be required to support MDD DD’s* |
| EC MDR Design Examination Certificate | • Submission of MDR DD (maybe based on MDD DD)  
|                                           | • New submission for up-classified devices (class III)  
|                                           | • Include renewal data  
|                                           | • DD review against MDR requirements  
|                                           | • *Will there be MDCG review?? MS/EC oversight??*  
|                                           | • Issue EC MDR DE Certificate (*post MDR QA Certificate*) |

### IVDD to IVDR Transition – Take account of significant reclassification
EU Joint Action Plan for Immediate Action

- **Notified Bodies**
  - Competence and tasks
  - Reassessment of NB’s dealing with high-risk devices
  - Joint audits by MS and EC

- **Post Market**
  - MS reinforcement
  - Vigilance coordination
  - EC analysis benchmarking

- **Co-ordination and Transparency**
  - Coordinated inspections, trends and analysis
  - International coordination IMDRF
  - Traceability (UDI)
Any Questions

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