New European Regulations on medical devices

Perspective of the HPRA, Ireland

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8th China International Medical Device Regulatory Conference

16th August 2017, Hangzhou.
Post-meeting note

The HPRA were invited to present at the China International Medical Device Regulatory conference on the new EU Regulations on medical devices as a guest of the China Food and Drug Administration (CFDA) and the China Centre for Food Drug International Exchange (CCFDIE).

This presentation represents the views and perspective of HPRA on the new EU Regulations on medical devices and in-vitro diagnostics and does not represent an official European view.

This was clearly stated during the presentation introduction.

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The references provided for each topic are intended only as a guide and should not be read in isolation. The reader must ensure that they are familiar with all the relevant parts of the Regulations and have considered the impact of the Regulations as a whole.

Additional text boxes have been added to some of the slides of this presentation to cover specific points or emphasis made by the speaker.
Regulation (EU) 2017/745 & 2017/746
Post-meeting note – Important changes to the existing medical device classifications rules in addition to 5 new rules – need to do a portfolio analysis. Change more profound with introduction of IVD classification system – which is similar but is not identical to GHTF system.

Classification changes

MDR - 22 rules (5 new)

IVDR – new rules based system (7 rules)

Clarification on implementing rules

Definitions updated

Provisions for qualification of products

<table>
<thead>
<tr>
<th>Risk</th>
<th>MDR Classification</th>
<th>IVDR Classification</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>III</td>
<td>D</td>
<td>Surgical meshes Spinal disc implants HIV ABO grouping</td>
</tr>
<tr>
<td></td>
<td>IIb</td>
<td>C</td>
<td>Infusion pumps Companion diagnostics</td>
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<tr>
<td></td>
<td>IIa</td>
<td>B</td>
<td>SAMD Pregnancy self test</td>
</tr>
<tr>
<td></td>
<td>I</td>
<td>A</td>
<td>Reusable surgical devices Specimen receptacles</td>
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</table>
Post-meeting note – new Regulations build on the EU joint assessment process for notified bodies which has been very successful in improving the consistency and performance of notified bodies since introduced as part of the 2012 EU Commission Joint Plan for Immediate Actions

Ref: Reg. (EU) 2017/745 Articles 35-49, Annex VII
**Post-meeting note** – These are based on HPRA estimates as part of our resource calculations for joint assessment.

**Notified bodies – designation timeline**

- **Estimated applications**: 50 for MDR, 25 for IVDR
- **Initial assessment at national level**: December 2017 - January 2018
- **Referrals to EU joint assessment**: January 2018 onwards
- **Possible first designation proposals to MDCG**: May 2019
- **Full application of MDR**: May 2020
- **Full application of IVDR**: May 2022

**Estimated end-end process ≈ 18 months**

HPRA working with Commission & EU authorities:
- Ensure process, systems & implementing legislation are ready in time
- Address capacity & build capability
- Coordinate & plan work – ensure equity, fairness, effective assessments

*Ref: Reg. (EU) 2017/745 Articles 35-49, Annex VII*
**Post-meeting note** — the new Regulations place additional responsibilities and obligations on all parties in the sector. This slide provides a summary of the specific requirements outlined for manufacturers and authorised representatives in Chapter II. Other requirements will apply to these and other entities across the Regulations.

## Economic Operators Obligations

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Authorised Representatives (AR)</th>
<th>Person Responsible for Regulatory Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Article 10</td>
<td>• Article 11</td>
<td>• Article 15</td>
</tr>
<tr>
<td>• Quality management system</td>
<td>• AR within the EU</td>
<td>• Demonstration of expertise</td>
</tr>
<tr>
<td>• Risk management</td>
<td>• Written mandate – clear tasks</td>
<td>• Available within organisation</td>
</tr>
<tr>
<td>• Clinical evaluation/PMCF</td>
<td>• AR legally accountable if the manufacturer fails to meet obligations</td>
<td>• Applies to Manufacturer and Authorised Representatives</td>
</tr>
<tr>
<td>• Continued updates</td>
<td>• Responsible Person</td>
<td>• Responsible for checking conformity of devices</td>
</tr>
<tr>
<td>• UDI &amp; registration</td>
<td></td>
<td>• Updates to technical documentation</td>
</tr>
<tr>
<td>• Labelling &amp; language</td>
<td></td>
<td>• PMS obligations</td>
</tr>
<tr>
<td>• Incident reporting/FSCA</td>
<td></td>
<td></td>
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<tr>
<td>• Obligation to act</td>
<td></td>
<td></td>
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<tr>
<td>• Periodic reporting</td>
<td></td>
<td></td>
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<tr>
<td>• Liability cover for damage compensation</td>
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</tbody>
</table>

*Ref: Reg. (EU) 2017/745 Chapter II, especially Article 10, 11, 15*
Post-meeting note – the new Regulations place a huge focus on increased availability of information on the identification, performance & safety of devices. EUDAMED will be a key component of this.

MDR EUDAMED

Increase accessibility – different access levels
Significant development work across all modules

Ref: Reg. (EU) 2017/745 including Article 33, Annex VI
**Unique Device Identification**

UDIs will be issued for all devices, except custom-made and investigational devices.

The Commission will designate UDI issuing entities (e.g. GS1, HIBCC, ICCBBA).

Staggered application of labelling requirements.

- **Class III & implantable**
  - 2021

- **Class IIa & IIb**
  - 2023

- **Class D IVD**
  - 2025

- **Class I**
  - **Class B & C IVD**
  - 2027

**Post-meeting note** – HPRA are hopeful that further guidance on the practical application of UDI in line with the Regulations will be developed at EU level soon and that this will be consistent and will help inform international approaches to UDI application.

Ref: Reg. (EU) 2017/745 including Article 27 & 28, Annex VI
Clinical data

Scientific approach to ongoing collection of clinical data which requires robust evaluation

Clinical investigations required for implantable and class III devices

Use of clinical data from equivalent devices needs to be valid and clearly documented

Common specifications will have an important role in defining clinical data requirements

Ongoing updating and reporting of clinical data – clinical evaluation report, PMCF evaluation report, summary of safety and clinical performance

Post-meeting note – significantly increased detail on approach to clinical investigations and evaluation of medical devices is outlined. Need to review existing clinical evaluation using current best practices and identify on a case-by-case basis whether the clinical data available is sufficient.
**Additional pre-market assessment**

Clinical evaluation consultation for certain implantable class III devices and active IIb which administer medicinal substances

For certain selected devices an additional 60 day period for review by expert panel or may decide after 21 days (criteria based) not to provide an opinion

Implantable class IIb devices must all now undergo an individual assessment

Increased emphasis on notified bodies issuing certificates within limited validity periods or specific conditions

Increased obligations on authorities for technical and clinical review of all devices during notified body assessment and ongoing market surveillance activities

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**Post-meeting note** – while the ‘scrutiny’ mechanism was subject to a lot of discussion there are also a number of other important changes relating to the pre-market assessment of medical devices and also the ongoing assessment of technical files and clinical evaluations by notified bodies & regulatory authorities.
Coordinating a decentralised system

Post-meeting note

Coordination is of critical importance in a decentralised regulatory system which is reliant on consistency in the application of the legislation across Europe.

One of the key challenges that the EU regulatory system has faced over the years is coordination of the way in which the current Directives are implemented and applied at each national level, in each country across the European Union and with our partners within the EEA/EFTA area and other trade partners.

Significant improvement has been made in coordination over the last number of years in particular since the introduction of the joint plan for immediate actions and the reformulation of the network of Competent Authorities for Medical Devices (CAMD). This has also allowed for initiation of a number of joint actions on medical devices part financing by the European Health Programme.

The new Regulations place significant further emphasis on governance, coordination and work-sharing between authorities across the EU.

The HPRA believe that it is critical for authorities to work together, closely with the EU Commission, to ensure that we approach implementation in a clear and consistent manner. HPRA has been instrumental in initiatives to try to set implementation priorities at EU level.
Post-meeting note – the EU Commission has kindly provided permission for this slide to be used to outline the key priorities and ongoing work on implementation – some of which was already underway before publication of the final texts. The notified body requirements and MDCG are required by 26th November 2017.
**Post-meeting note** – this graphic was prepared by the HPRA based on its views of the relationships between different entities within the regulatory system. The relationship and cooperation between the EU Commission and the Competent Authorities is key.

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**Governance**

- **DG GROW - POLICY & IMPLEMENTING LEGISLATION**
- **DG SANTE - NOTIFIED BODY JOINT ASSESSMENT**
- **DG RESEARCH - JOINT RESEARCH CENTRE - TECHNICAL SUPPORT**

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**REFERENCE LABS**
- Scrutiny procedure
- Technical/scientific input to network
- Advice to innovators
- Common specifications
- Verify claimed performance of IVDs (class D)
- Batch testing
- Development of testing & analysis methods for market surveillance
- Reference materials

**EXPERT PANELS**

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**EUROPEAN COMMISSION**

**COMPETENT AUTHORITIES**

**MEDICAL DEVICE COORDINATION GROUP (MDCG)**
- MDCG tasks
  - Oversight
  - Guidance development
  - System development
  - Policy advice

**TECHNICAL WORKING GROUPS**
- Classification
- Clinical
- EUDAMED
- Notified bodies
- Market surveillance
- Vigilance
- Standardisation/CTS

**INTERNATIONAL REGULATORS**

**COMPETENT AUTHORITIES FOR MEDICAL DEVICES (CAMD)**
- CAMD role
  - Implementation planning
  - Communication
  - Best practice development
  - Training
  - Peer review
  - Joint actions
  - Coordination
  - Strategic development

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Ref: Reg. (EU) 2017/745 Chapter VIII
Post-meeting note – HPRA has been allowed to present this draft model which is currently under discussion at EU level for new working group structures under the MDCG. The importance of notified bodies being part of the regulatory system is highlighted as is the importance of engagement with stakeholders.
Cooperation & joint working

Network of EU Competent Authorities working closely with EU Commission

Develop common understanding & approach to implementation of new Regulations

Contributing to identification and prioritisation of implementation steps – EU level

Roadmap of priorities to be published later in 2017

Mechanism for communication with stakeholder groups

Post-meeting note – CAMD has been working to try to ensure implementation is effective and prioritised. CAMD can provide a forum for developing a common understanding between the authorities on the practical aspects of the regulations and to develop best practice approaches to implementation.
Advice for manufacturers

Post-meeting note – key advice for manufacturers is to start planning now, if you haven’t already, for the new Regulations. Understand the implications across your product portfolio. In particular review your clinical evaluations and current PMCF plans and ensure they are ‘state of the art’ and then assess the implications of the requirements as outlined in the new Regulations.

Comprehensive planning, prioritisation & portfolio analysis
Analysis of supply change partners & relationships with other economic operators e.g. ARs
Review & update of clinical evaluations & PMCF

Review of labelling requirements & UDI
Review of technical requirements/classification and applicability to product portfolio
Quality management system

Person responsible for regulatory compliance
Seek advice & clarification
**Post-meeting note** – a key point here is the impact of the new Regulations on existing certificates. Certificates for devices which have been validly issued under the existing Directives are valid for the period of time specified on the cert (i.e. for up to 5 years) – however they will all become void in 2024. Significant changes or modifications to existing devices after 2020 though will have to comply with MDR.

### Transition period

- **05-05-2017**
- **26-11-17**
- **26-05-18**
- **26-05-2020**
- **26-05-2022**
- **05-2024**

**Publication of Regulations in Official Journal of European Union**

**Notified body requirements MDCG**

**Cooperation between authorities**

**Full application of MDR at 3 years**

**Full application of IVDR at 5 years**

**Existing certificates can be re-issued for up to 5 years**

**Existing certs void after 4 years from full application of MDR and 2 years for IVDR years**

*Ref: Reg. (EU) 2017/745 Article 120 and Article 123*
Post-meeting note – One of HPRA's key priorities is to build awareness and ensure an understanding of the new Regulations in the sector. HPRA's website will be used as an active resource for information in addition to other information mechanisms. HPRA are happy to receive queries on the new Regulations – we cannot commit to know the answers to them all but identifying the key questions and challenges is also important.

Further information & advice

http://www.hpра.ie/homepage/medical-devices/  email @ mdr-ivdquiries@hpра.ie
**Post-meeting note** – the EU Commission’s website is also another useful resource and information source.

Further information & advice

The role of medical devices is essential to the healthcare of EU citizens. The diversity and innovativeness of this sector contributes significantly to enhancing the safety, quality and efficacy of healthcare in the EU.

Covering a wide range of products, from simple bandages or sticking plasters to the most sophisticated X-ray equipment, the medical devices sector plays a crucial role in the diagnosis, prevention, monitoring and treatment of diseases. It also helps improve the quality of life of those with disabilities.

The importance of the medical devices sector

The medical devices sector helps save lives by providing innovative health care solutions regarding diagnosis, prevention, monitoring, treatment and alleviation of disease. The sector has become increasingly important for the healthcare of EU citizens and an influencer of expenditure.

- The medical devices industry is a major employer in Europe, employing 575,000 people in the EU.
- Total sales amount to EUR 100 billion.
- The sector represents some 25,000 companies, of which 95% are Small and Medium-sized Enterprises (SMEs).

Challenges faced by the sector

The medical devices sector faces many challenges at national, European and international level, which may have an impact on their innovation capacity and overall competitiveness:

- **Public Health Systems**
  - In particular, emerging needs such as developing a shared understanding of healthcare goals, overcoming health inequalities, an ageing society and exploiting the potential of e-health technologies.

- **Finding the balance between patient’s needs and financial sustainability**
  - Ensuring that the sector can enhance better access for patients to devices whilst simultaneously ensuring that pricing and reimbursement policies are effective;
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