RAPS MDR/IVDR Workshop Feedback – Brussels 16/17 May 2018

Presentation by Paul Brooks
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RAPS Brussels Workshop

(the following slides utilize information drawn from the following presenters)

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- Gert Bos, **Qserve Group**
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Current Status

• 30,000 feet view
  – Current practices and guidances
• Known knowns, known unknowns, unknown unknowns *(Donald Rumsfeld)*
• Stakeholders working together
• Identifying key challenges
• Many questions don’t have all the answers
• No grandfathering
Consider Simultaneous Occurring Waves

Bassil Akra
Interpretation of EU Regulations

Manufacturer interprets/implements MDR
Advice/input from experts, consultants, CAs, NBs* (NB* - must maintain independence/objectivity)

Notified body assesses/evaluates the manufacturers solutions

Competent authority/EC audit the notified body reviews/assessments

Courts can provide interpretation (rarely needed)
Key Dates – Notified Bodies

- **Nov 2017**: NBs apply for designation. Not transparent which NBs and what scopes/codes.

- **Q1 2019**: NBs receive (initial?) MDR NB scope designations.

- **May 2019**: MDR transition period ends. Devices with existing MDD CE Marking certificates.

- **May 2024**: MDR grace period ends.

**Now to?**

- NBs - Joint Assessments. Not transparent which NBs and outcomes.
EC Context

• Directives are old need review
  – Some inconsistency in implementation
• Almost record length negotiations
• Requirements are demanding, but, not as dramatic as they could have been
EC Implementation Priorities

- Designation of notified bodies
- Governance (MDCG, WGs, expert panels)
- EUDAMED
  - Very ambitious requirements
  - Significant concern about design and development in time (for now focus on the essentials)
  - Unique and challenging to build/run
- UDI
  - Taking account of US experience, IMDRF and other RAs
  - Seeking a more harmonized approach
- CS on Annex XVI & CS on reprocessing (both advanced)
- Communication (including third countries)
Notified Bodies

• Applications 26 November 2017
  – Many have applied (EC does not have direct oversight)
  – Some NBs leaving, some new NBs applying

• Some have had initial joint assessments
  – Non-conformities may have be raised
  – Designation of some notified bodies may occur soon (Q1 2019?)

• Concern about transparency on applied designation scopes and adequate coverage
Governance

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

EUROPEAN COMMISSION

COMPETENT AUTHORITIES

MEDICAL DEVICE COORDINATION GROUP

INTERNATIONAL REGULATORS

COMPETENT AUTHORITIES FOR MEDICAL DEVICES

REFERENCE LABS

EXPERT PANELS

Expert panels/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

MDCG tasks
- Oversight
- Guidance development
- System development
- Policy advice

TECHNICAL WORKING GROUPS

CAMD role
- Implementation planning
- Communication
- Best practice development
- Training
- Peer review
- Joint actions
- Coordination
- Strategic development

TECHNICAL WORKING GROUPS

TECHNICAL WORKING GROUPS
EUDAMED

• EC expect to be ready by Spring 2020
• In event that Eudamed is not fully functional: Article 123(3)(d) specifies which Articles are postponed
• Use of Eudamed system that is postponed (upload) not the obligations
• Eudamed is a ‘monster’ or ‘bit of a beast’
  – A lot has been done, focused on meeting minimum needs
<table>
<thead>
<tr>
<th>TBD – Changing Field of Play</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delegated Acts</td>
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<tr>
<td>Implementing Acts</td>
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<tr>
<td>Common Specifications</td>
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<tr>
<td>Harmonized Standards</td>
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<tr>
<td>Guidance Documents (MEDDEV etc.)</td>
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</table>
EC Implementing/Delegated Acts

• Potentially 80 empowerments, unlikely that all will be needed (18 are mandatory, but, will not necessarily be in place for the date of application)

• MEDDEV-like guidance is useful, consensus documents (new MDR/IVDR much more prescriptive, but, still gray areas regarding guidance)
  – 30 years to put in place what we have against MDD/IVD, will take time for MDR and IVDR
Timeline

• Deadlines in place now very tight required by EU stakeholders (including the EP)
• Challenging to meet for EC, MS, NB and manufacturers
• No extensions possible unless there is strong evidence that the system is not working
  – Parliamentary elections in May 2019?
• We all need to deal with it!
CAMD

• Competent Authority for Medical Devices network
  – Best practice, consistency across CA’s
  – Improving inter-CA cooperation/collaboration

• EU will remain a decentralized regulators
  – Requires confidence in CE Marking
  – Confidence in other CAs and NBs
CAMD MDR/IVDR Implementation Roadmap

CAMD Implementation Roadmap

- MDR/IVDR –
  - CAs avoiding deviation – not perfect texts – guidance is needed
- CAMD taskforce (originally led by MHRA, UK)
- 46 different line items – 8 technical clusters
- Multiple parties (WG’s) and other stakeholders
- Identifies challenges and priorities
  - clinical evidence, classification, IVD, market surveillance etc.
## CAMD Working Groups

<table>
<thead>
<tr>
<th>Activity</th>
<th>Recommended responsible parties/ owners</th>
<th>Priority level</th>
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</thead>
<tbody>
<tr>
<td>2.1 Classification guidance for IVDs around classification rules and scope, giving practical examples</td>
<td>IVD WG, C&amp;B WG, Software WG</td>
<td>High</td>
</tr>
<tr>
<td>2.2 Information and guidance on classification for MDs (changes on classification rules)</td>
<td>C&amp;B WG, Software WG, NET WG, IVDWG</td>
<td>Medium</td>
</tr>
<tr>
<td>• Information to highlight changes to classification rules</td>
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<tr>
<td>• Guidance on new classification rules/ changes to existing rules e.g. MEDDEV 2.4/1 update/addendum</td>
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<td>• Software classification guidance (refer to workstream 2.1 IVD Classification)</td>
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<td>2.3 Common specifications for annex XVI products for MDs</td>
<td>COM ad hoc WG, MDCG, NBOG</td>
<td>High</td>
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<tr>
<td>2.4 Implementing act on reprocessing SUDs for MDs</td>
<td>COM, MDCG</td>
<td>Medium</td>
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<tr>
<td>2.5 Guidance for combination products and companion diagnostics around appropriate level of interaction with relevant authorities (ref: 3.4)</td>
<td>C&amp;B WG, IVD WG, (HMA-CAMD borderline WG, EMA, medicines CAs, tissues &amp; cells CAs, EDQM), NBOG</td>
<td>Low</td>
</tr>
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</table>
CAMD & WGs – Work Plans

• CAMD executive group coordinating with WGs chairs and reviewing work plans
• Chairs are translating the work items work plans – deliverables and timelines
• New inquiry form (ITF) – to be on the CAMD website – how and who will respond TBD
WG Plan Example

MDR / IVDR Implementation Work Programme of EU WG on Clinical Investigation and Evaluation

This document sets out, in summarised form the work programme of the Clinical Investigation and Evaluation Working Group (CIE WG), with respect to the implementation priorities for Regulation 2017/746 on Medical Devices and, where relevant Regulation 2017/746 on In Vitro Diagnostic Devices. This work programme has been developed from the previous CIE work programme and it was developed following input received at the November 2017 CIE meeting. This work programme also takes into account the implementation roadmap which has been developed by the CAMD (Competent Authorities for Medical Devices) Implementation Taskforce.¹

Further detail with respect to the following objectives is contained in specific terms of reference (TOR):

- Clinical evaluation work package
- Summary of safety and clinical performance
- Template development and EUDAMED

Activities are organised by objectives and deliverables to provide a summary of ongoing work items. This work programme will be updated following the next CIE WG meeting in April 2018.

<table>
<thead>
<tr>
<th>No.</th>
<th>Objective</th>
<th>Deliverable</th>
<th>Output / Next Steps</th>
<th>Time</th>
<th>Lead</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Clinical evaluation work package (CAMD priority – high)</td>
<td>Gap analysis rev 4 / MDR</td>
<td>Gap analysis for discussion</td>
<td>NCA discussion paper</td>
<td>April 2017 (complete)</td>
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<td></td>
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<td>Definition of – equivalent (UK), sufficient clinical data (IE), “legacy devices” (IE)</td>
<td>Guidance documents on specific topics</td>
<td>Separate document / Addendum</td>
<td>April 2018 (first draft including consultation)</td>
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<td>UK to host meeting end January Input – NBG stakeholders</td>
<td>Written endorsement for MDCG second meeting</td>
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¹ For further, see: [http://www.camd-europe.eu/sites/default/files/project_files/NEWS_171107_MDR-IVDR_RoadMap_v1.3.pdf](http://www.camd-europe.eu/sites/default/files/project_files/NEWS_171107_MDR-IVDR_RoadMap_v1.3.pdf)
Examples of WG Questions

<table>
<thead>
<tr>
<th>Topic</th>
<th>Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certificate Validity</td>
<td>Scenarios – place on-market pre-MDR/IVDR, Certified during transition period</td>
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<tr>
<td>Certificates of Free Sale</td>
<td>Length of validity during transition</td>
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<tr>
<td>Implant cards</td>
<td>Content, symbols, language</td>
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<tr>
<td>Vigilance</td>
<td>Timeframes and parallel systems</td>
</tr>
<tr>
<td>IVDs</td>
<td>Clinical evidence: Scope codes: Classification</td>
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<tr>
<td>Systems</td>
<td>Eudamed, UDI and national databases</td>
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<td></td>
<td>Parallel systems in place during the transition</td>
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<tr>
<td>Governance</td>
<td>Resources, expertise, establishing expert panels</td>
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<tr>
<td>NB bottlenecks</td>
<td>Joint assessments, application process, scheduling JAs, Brexit</td>
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<tr>
<td>Clinical</td>
<td>Sufficient clinical evidence, equivalence, IVD performance evaluation</td>
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</tbody>
</table>
# In Progress

<table>
<thead>
<tr>
<th>WG</th>
<th>Work item</th>
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</thead>
<tbody>
<tr>
<td>Clinical investigation &amp;</td>
<td>Sufficient clinical evidence</td>
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<tr>
<td>evaluation WG</td>
<td>Equivalence</td>
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<tr>
<td></td>
<td>Summary of Safety &amp; Clinical Performance</td>
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<td>Templates – CEAR, Cl assessments, PMCF plan</td>
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<td>COEN WG</td>
<td>Custom made devices – definitions and terms</td>
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<td>Class I MDs - outreach</td>
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<td>Market surveillance issues</td>
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<td>IVD technical group</td>
<td>Classification</td>
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<td>Clinical evidence for IVDs – concepts definitions</td>
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<td>Companion diagnostics</td>
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<td>NB conformity assessment provisions</td>
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<td>NBOG</td>
<td>NB designation scopes</td>
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<td>Templates for JA</td>
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<td>Communication with NBs</td>
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<td>Training of assessors</td>
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<tr>
<td>Software WG</td>
<td>Draft plans translating roadmap</td>
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<tr>
<td>UDI WG</td>
<td>Draft plans translating roadmap</td>
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<tr>
<td>Vigilance WG</td>
<td>Gap analysis – previous MEDDEV</td>
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<td>Template reports – MIR, PSUR, FSCA, trend reports</td>
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</tbody>
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CAMD Transitional Subgroup

- Temporary subgroup
- Identify and address potential inconsistency in interpretation/application of MDR/IVDR
- Provide recommended interpretations
- Three meetings in Brussels
- FAQ
Some Dates

• Registration
  – MD Nov 2021
  – IVD Nov 2023

• UDI carrier 26 May:
  – MD 2021/2023/2025
  – IVD 2023/2025/2027
Key Concerns

- Brexit
- Managing economic operators – contract revisions
- Designation of notified bodies
- Notified bodies being restricted in sharing expectations (until designation)
- Legacy devices
- Understanding the CAMD roadmap and arrival times
- Regulation extension – business decisions made now cannot easily be reversed
- Impact on registrations elsewhere
- Clinical evidence – ‘sufficient’
- ‘Combination’ devices
Final Thoughts

- Lots of uncertainty, ambiguity, lack of guidance, changing requirements, NB expectations
- Lots of expert opinions, but, no-one has done it
- No time to wait
- Some apprehension about making mistakes
- We will make mistakes
- Best foot forwards!
Thank you

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