Current status and the (current) indications

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Disclosure

Speaker name: Pedro Eerdmans

I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☒ I do not have any potential conflict of interest
The Notified Body Kitchen
Current situation
NB worries

headache
NB worries: regulatory system readiness
Expert panels

1. Orthopedics, rehabilitation & rheumatology
   - 3 device specific subcategories
2. Cardiovascular / lymphatic
   - 5 device specific subcategories
3. Respiratory, anesthesiology, intensive care
4. Neurology
   - 3 device specific subcategories
5. Endocrinology and diabetes
6. General and plastic surgery
   - 3 device specific subcategories
7. Obstetrics & gynecology including reproductive medicine
8. Gastroenterology and hepatology
9. Nephrology and urology
10. Ophthalmology
11. Emerging and new technologies
12. In-vitro diagnostics (IVDs)
13. Dentistry
NB worries: workload

- The workload is probably around 30,000 MDD + AIMD certificates.
- Knowing that recertification and surveillance risks will take significantly longer than usual. Increasing number of days to complete one single technical documentation review
- Notified bodies are not in a position to accept application for many high-risk products (those that are needed the expert panels and EU reference to be designated. Expert panels and EU reference labs need to be in place to issue any MDR certificate for Class III implants)
- (If) EUDAMED is late, a lot of procedures will need to be adapted (the ones related to process clinical, vigilance, PMS data).
NB worries: Brexit

- 30-40% CE marked through UK notified bodies.
- Tens of thousands of products risks.

- Blood Safety (IVDs)
  - 80-90% of IVDs used in blood safety certified by UK notified bodies.

- 50-60% of Orthopaedic implants used in the EU are certified by UK notified bodies.
  - In particular, hip replacements, knee replacements and spinal implants are particularly affected.
Some of the MDR consequences

Although this paper presents complete survey results and guidance on next steps, some significant highlights from our research include:

- **Only 28% of respondents** with revenue of more than $1 billion plan to declare full MDR compliance by May 2020.

- **57% of respondents** are still in the process of renewing their MDD certificates so they can leverage the much-needed transitional provisions (noted in Article 120 of the EU MDR).

This is not to say that industry is sitting idle. The amount of work and time required to fully remediate outweighs industry efforts thus far. It is of note that, in the 2019 KPMG/RAPS survey, respondents said the top two barriers to achieving MDR compliance were:

1. Lack of available timely guidance from the European Commission
2. Lack of internal resources

Given these two concerns, it is reasonable to believe MDR will negatively impact not only the costs of medical devices, but also manufacturers’ ability to innovate. Specifically:

- **36% of respondents** estimate $5 million in expenditures to achieve EU MDR compliance

**More than 50% of respondents** said they are planning on first/development product launches outside of Europe.

- **66% of respondents** have not started planning for the long-term organizational impacts of EU MDR, despite significant investment to date in remediation activities

**EU MDR Timeline**

- **March 2019** Translation to ISO 13485:2016 must be completed
- **May 2024** Required for all EC certificates issued 5 years from the issued renewal date or 4 years from the MDR date of application (May 27, 2020), whichever comes first

- **May 2020** MDR date of application
- **May 2025** Devices certified under the MDD can no longer be sold or distributed

The race to EU MDR compliance continues.
Potential effect on current products.

**Significant percentage of medical device organizations plan to withdraw/discontinue product currently sold in EU**

% of respondents to 2019 annual KPMG/RAPS survey

- Yes: 43%
- No: 57%
To be continued
Thank you for your attention
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