Industry Reaction to New EU Regulations

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A Promise for Life

Overview

Thank you for the opportunity to share my perspectives on the Medical Device Industry's reaction to the Medical Device Regulation proposal.

This presentation includes a summary of the Eucomed Postion Paper " Towards a regulation that guarantees patient safety, ensures patient access and keeps innovation in Europe". (www.eucomed.be/key-themes/medical-devices-directives)

It also represents my perspective as a regulatory professional with 30 years experience in the medical device and diagnostic industry. These comments reflect my personal opinion and do not represent the position of Abbott.

My perspectives have been shaped by multifunctional experience (R&D, Product Development, Quality and Regulatory) in Medical Diagnostics and Device businesses.

Industry Reaction to Proposed Medical Device Regulation

Overview of Eucomed Position Paper on the Medical Device Regulation Published 26 Sep 2012

What Does Industry Want?

Points to Consider on How to Prepare

Overview of Eucomed Position Paper

September 26, 2012 – draft Medical Device Regulation was published

January 30, 2013 – Eucomed position paper was published

"Towards a regulation that guarantees patient safety, ensures patient access and keeps innovation in Europe"
http://www.eucomed.be/key-themes/medical-devices-directives

Eucomed's response to the Commissions's proposal for the revision of the EU Medical Devices Directives

Overview of Eucomed Position Paper

" Towards a regulation that guarantees patient safety, ensures patient access and keeps innovation in Europe . http://www.eucomed.be/key-themes/medical-devices-directives "

Industry acknowledges the need for change

- Industry fully supports the European Commission's proposed measures as they are absolutely essential to identify and address potential safety and quality issues at the earliest possible stages.

Industry agrees with many measures in the Commission proposal

Industry believes that more stringent measures are necessary to ensure the highest safety of medical technology for Europeans. However, industry believes this should be done through additional systematic control procedures on the work undertaken by Notified Bodies.

Overview of Eucomed Position Paper

" Towards a regulation that guarantees patient safety, ensures patient access and keeps innovation in Europe . http://www.eucomed.be/key-themes/medical-devices-directives "

Industry wants a **clear, predictable and effective** regulatory system specifically tailored for medical devices that…

Guarantees the highest level of **safety** for patients;

Ensures **timely access** to the latest innovative technologies;

Enjoys the **trust** of its stakeholders;

Contributes to the **sustainability** of national healthcare systems;

Maintains an environment, which encourages and keeps **research** and **innovation** in Europe.

Overview of Eucomed Position Paper - 7 Key Focal Areas

" Towards a regulation that guarantees patient safety, ensures patient access and keeps innovation in Europe . http://www.eucomed.be/key-themes/medical-devices-directives "

1. **Only the best Notified Bodies** should be allowed to approve medical devices

2. **A systematic control procedure** is necessary to improve the system and increase patient safety. Proposed scrutiny procedure (article 44) is not systematic and will not lead to increased patient safety.

3. **Increase stakeholder involvement** to ensure that the opinions of essential healthcare actors are heard.

Overview of Eucomed Position Paper - 7 Key Focal Areas

" Towards a regulation that guarantees patient safety, ensures patient access and keeps innovation in Europe . http://www.eucomed.be/key-themes/medical-devices-directives "

4. **Greater transparency and traceability** is critical to ensure that patients, doctors, industry and other stakeholders have access to clear information about the medical devices they use.

5. **Clarity on clinical evidence needs**

6. **Enhance vigilance and market surveillance** to allow for rapid identification of adverse events and to ensure coherent and timely action by Member States.

7. **Clear science based classifications** are needed to avoid the currently proposed reclassification of families of medical devices without any scientific or other justification.

Overview of Eucomed Position Paper - 7 Key Focal Areas

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- Any proposed measure should be assessed against 3 criteria:
  - Does it increase Patient Safety (avoid PIP)?
  - Does it maintain / enhance patient access to technologies?
  - Does it encourage innovation (sustain healthcare systems)?

- Article 44 'scrutiny' & 'PMA' solutions do not meet all of the 3 criteria proposed by Eucomed

Overview of Eucomed Position Paper

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Systematic Procedure for Class III

Measures to ensure notified bodies are doing a thorough and consistent job

- More rigorous criteria for class III Notified Body designation and monitoring
- Encourage further specialization of Notified Bodies
- Undertake more regular audits of class III designated Notified Bodies

Overview of Eucomed Position Paper

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Systematic Procedure for Class III

Measures to ensure that the clinical evidence for medical devices is being properly reviewed by independent clinical experts

- Medical Device Coordinating Group (MDCG) to vet and maintain a list of clinical experts
- Require Notified Bodies to engage only these vetted clinical experts
- Require Notified Bodies to publicly disclose their internal and external technical experts.
- Allow manufacturers and authorities to use clinical experts for scientific advice

New Medical Device Regulations

Change is Certain

Be Prepared

Points to Consider on How to Prepare

Educate

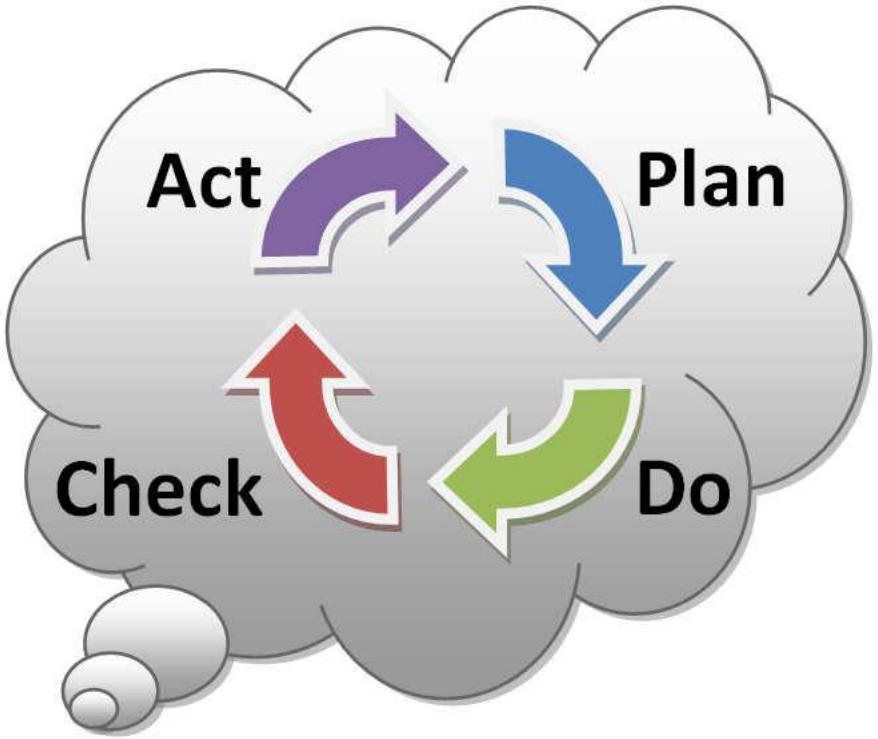
Assess

Plan

Do

Check

Act



Communicate…….Don’t Procrastinate

Educate and Communicate

Educate yourself

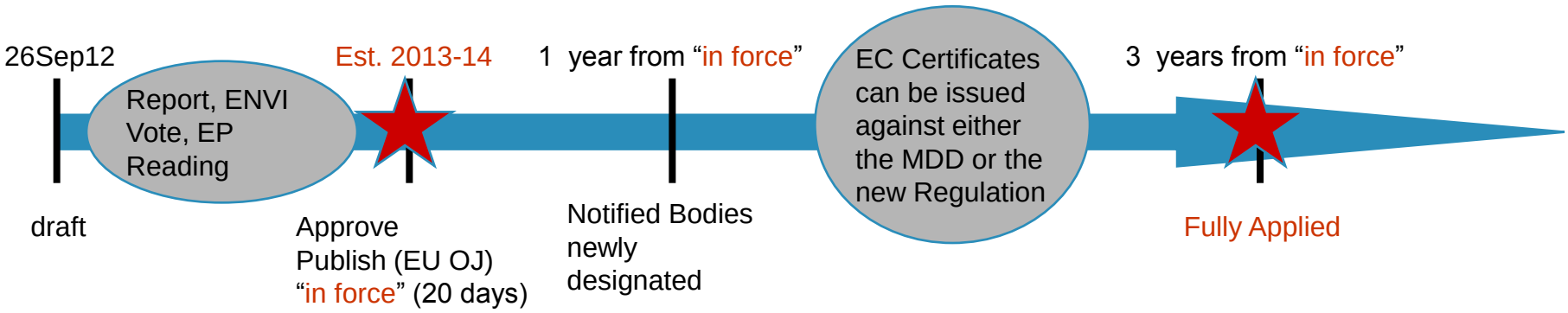
- Ask your Notified Body how they are preparing
- Study the proposed regulation, understand the transition and timing
- Read Industry opinion and publications
- Use the many opportunities exist for gathering information

Use your QMS Quality Planning Procedures to assess gaps and transition to the anticipated requirements

Establish a Communication Plan

- Educate your colleagues and management
- Share plans and status broadly and often
- Mark progress…… It is motivational

The Medical Device Regulation Timeline



Some Articles are applied immediately and are the subject of Immediate Actions

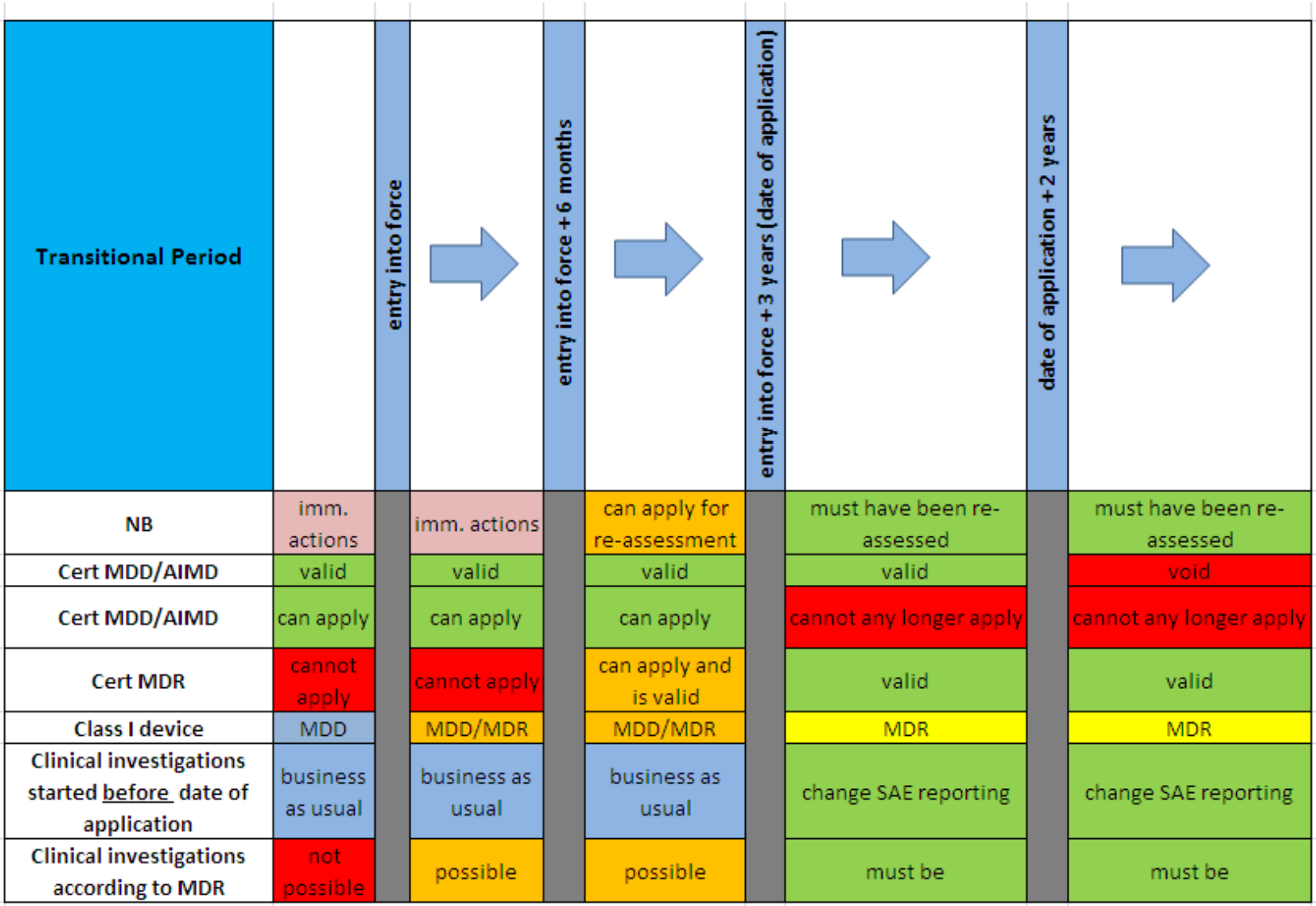
Notified Body designations under the MDD 93/42/EEC become void at the date of full application of the Medical Device Regulation

MDD EC Certificates issued **before** the regulation enters into force remain valid until expiration date

MDD EC Certificates issued **after** the regulation enters into force become void two years after the application of the regulation

Certificates issued against the new MD Regulation can be issued by designated NBs **before** the full application of the regulations

Regulation Transition is Not Simple



Transitional Period		entry into force		entry into force + 6 months		entry into force + 3 years (date of application)		date of application + 2 years	
NB	imm. actions		imm. actions		can apply for re-assessment		must have been re-assessed		must have been re-assessed
Cert MDD/AIMD	valid		valid		valid		valid		void
Cert MDD/AIMD	can apply		can apply		can apply		cannot any longer apply		cannot any longer apply
Cert MDR	cannot apply		cannot apply		can apply and is valid		valid		valid
Class I device	MDD		MDD/MDR		MDD/MDR		MDR		MDR
Clinical investigations started before date of application	business as usual		business as usual		business as usual		change SAE reporting		change SAE reporting
Clinical investigations according to MDR	not possible		possible		possible		must be		must be

Source: www.eucomed.org

QMS Quality Planning

Quality Plans are tools used to implement complex projects

Quality Plans provide for:

- The identification and acquisition of any controls, processes, equipment, resources, and technology
- Achievement of the required quality for the project
- Standards of acceptability for project deliverables and any resulting processes
- The identification and preparation of quality records and procedures specific to the project

Assess

Perform a gap analysis

- Determine where you need the most improvement
  - Immediate Actions
  - Key Changes in the requirements
  - Product and QMS Certifications

This will establish the scope of activity

Assess

Involve all areas of your company

- Regulatory
- Quality
- Vigilance
- Clinical
- R&D
- Operations
- Distributors
- Authorized Representatives

Assess
Consider Changes for Manufacturers

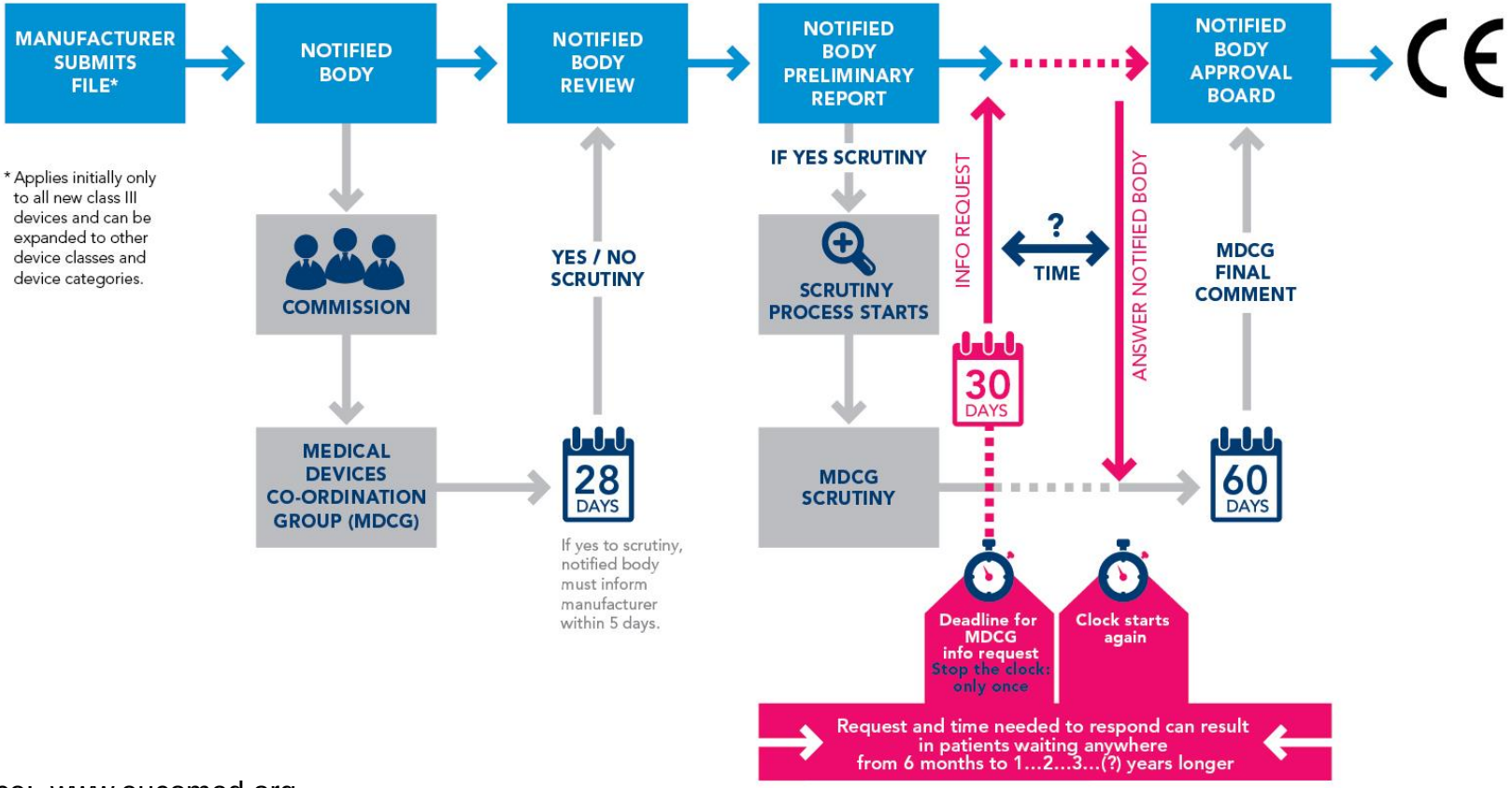
Examples Include:

- Establish Qualified Person (QP) at manufacturer, Authorized Representative, Importer
- Role of and requirements for importer and distributor
- Maintain databases to provide public information regarding: clinical studies, clinical data, product registration, subcontractors….etc.
- Distributor and Authorized Representative responsibilities

Assess
Consider Critical Elements of the Revision

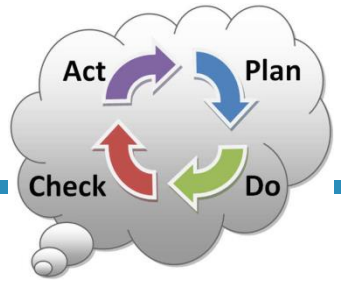
Governance (Commission role) – Medical Device Coordination Group
Scrutiny
Notified Body System
Vigilance Coordination
Standards/Common Technical Specifications/Guidelines
Transparency (databank; public info)
Stakeholder involvement
Traceability/Unique Device Identifier
Reprocessing
Clinical Data
Distributors/Economic Operators

Proposed Scrutiny Procedure (Article 44, Page 66)
Medical Devices Directives revision proposal



Source: www.eucomed.org

Plan



Use the gap analysis to prepare a project plan

- Prioritize areas that will take the longest to improve or require the greatest change in the organization
- Notified Bodies have immediate actions – be aware of how they may impact your organization
- Plan resources to effectively transition

Management engagement and endorsement is critical to success

Communication and coordination within the organization is key

- Communicate the project plan, status and changes in the proposed regulation broadly and often

Do

Establish a core team with responsibilities and timelines

Engage the whole organization

Communicate

Check

Keep current on changes in proposed Regulation

- Current proposal may be considered controversial in several areas – changes will come
- Make sure your company stays aligned with the regulation through implemention of changes

Re-assess gaps to procedures and practices periodically

- Determine where you still need improvement
- Change is an iterative process – allow time to check your new procedures

Act

Continue to improve your plan and be willing to make changes as necessary

The best plans allow for flexibility

Communicate changes in plan and progress to make sure all areas maintain coordination

Don’t Wait Too Long to Get Started

These are significant changes

They will take time to incorporate into your procedures, organizational structure, and product pipeline

Make sure that you start early and establish a structure for change and change management

Summary

A regulation that guarantees patient safety, ensures patient access and keeps innovation in Europe

Continue to educate yourself and your organization on the Regulation

Start the process for change – it takes time

Thank You!