The case of the 3 monkeys: “I don’t see, I don’t hear, I don’t speak”

EHRA Summit, Monday April 8th

J. Calle

The **three wise monkeys** sometimes called the **three mystic apes**, are a pictorial maxim.

Together they embody the proverbial principle to **"see no evil, hear no evil, speak no evil“**

The three monkeys are **Mizaru**, covering his eyes, who sees no evil; **Kikazaru**, covering his ears, who hears no evil; and **Iwazaru**, covering his mouth, who speaks no evil.
Sometimes there is a fourth monkey depicted with the three others; the last one, **Shizaru**, symbolizes the principle of **"do no evil"**. He may be shown crossing his arms.

There are various meanings ascribed to the monkeys and the proverb including associations with being of good mind, speech and action. In the Western world the phrase is often used to refer to those who deal with impropriety by turning a blind eye

“I don’t See:” Key decisions are taking place, as we speak, in Brussels

“Austerity: Healthcare in hardship”
(*EurActiv*)

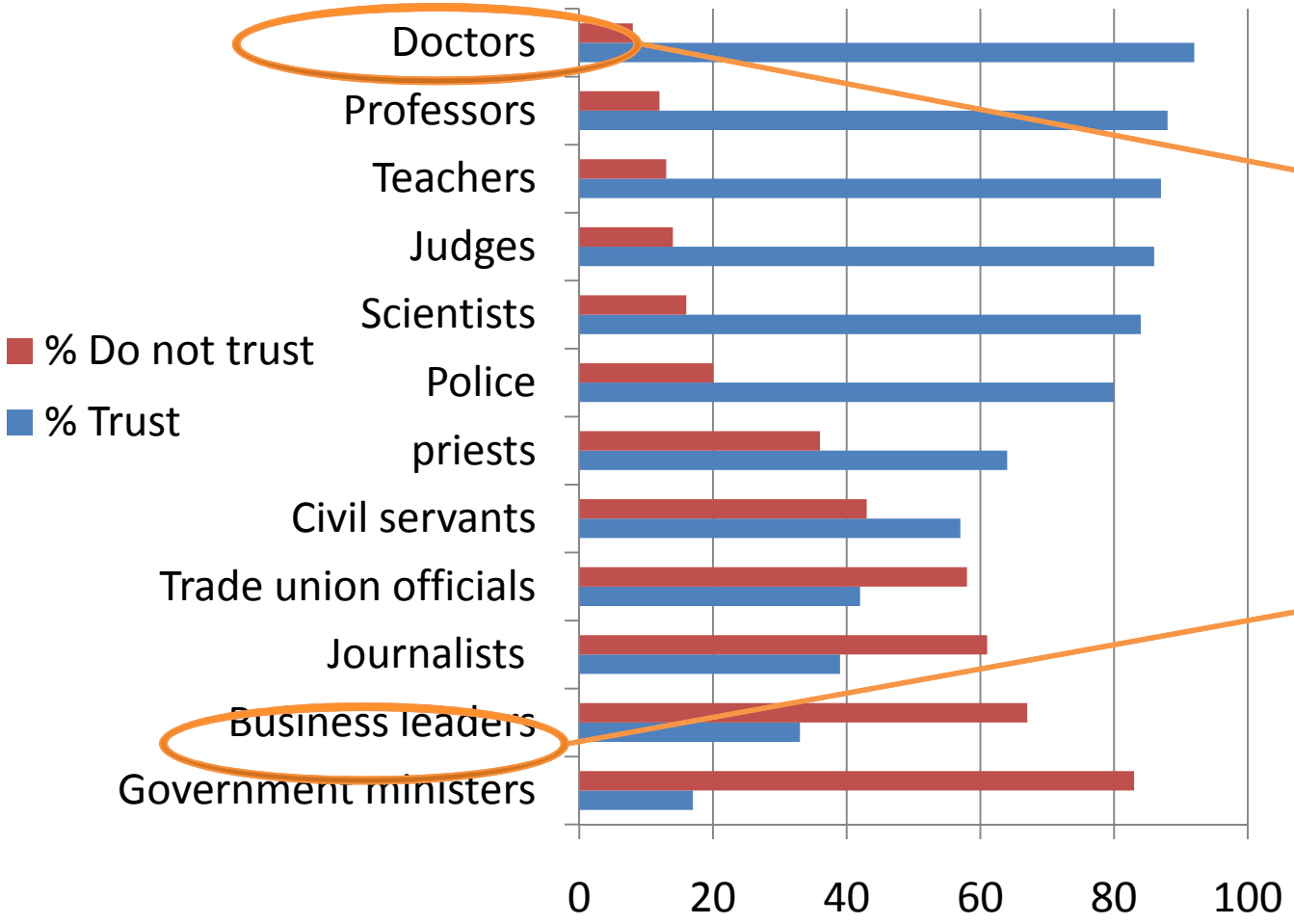
“European Parliament discusses Medical Devices.”
(*Eambes*)

“Healthcare and the economic crisis: Time for new thinking
(European Voice)

“Would privatising healthcare make it more innovative?”
(Debate Europe)

“I don’t hear:” Doctors have a grater chance to be listened to

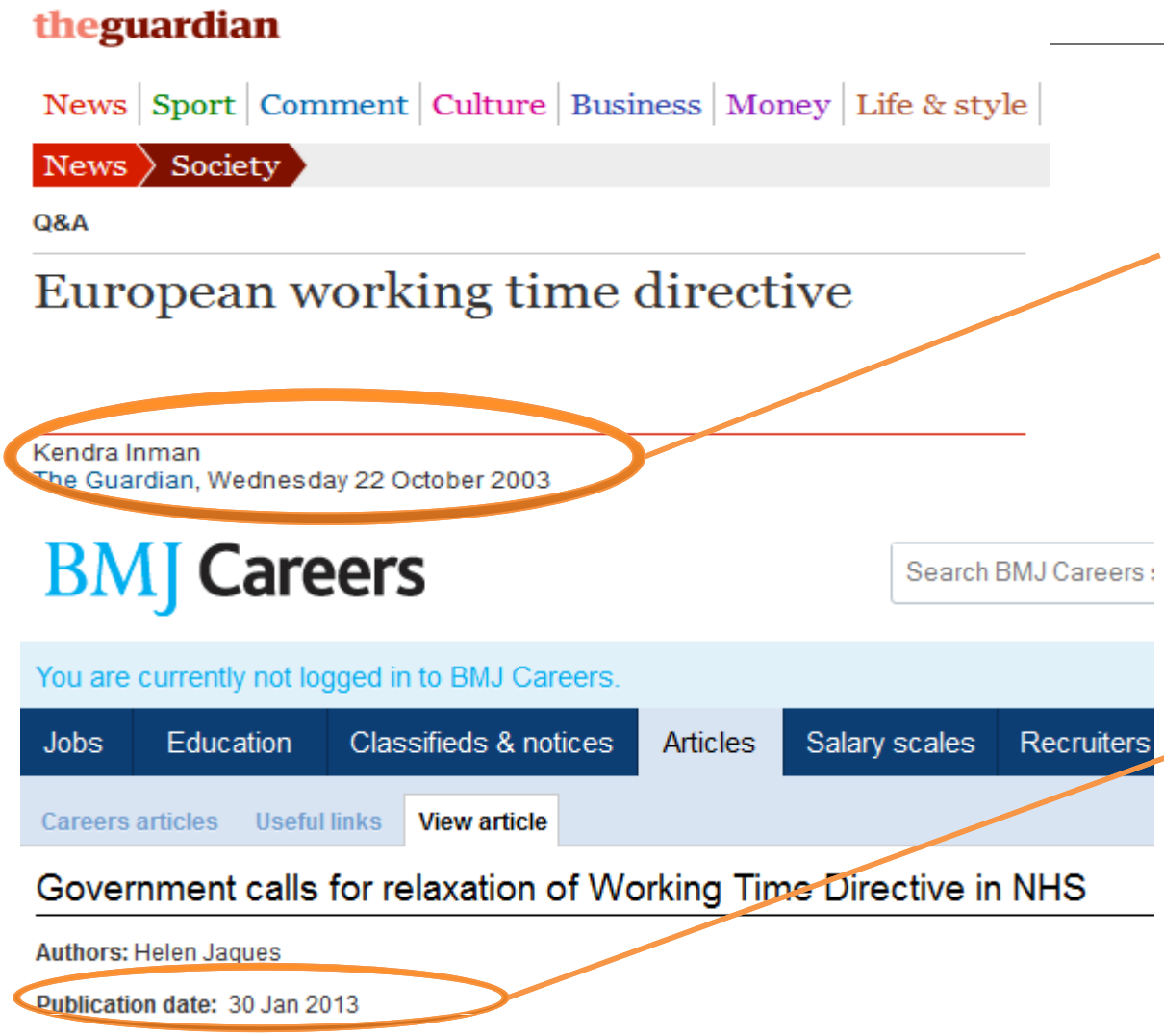
Trust Levels in Ireland (Source: MRBI Trust Survey 2010)



Doctors have a higher trust level than any other profession!

Sadly, the same can not be said for this second group of people…

“I don’t Speak:” The medical profession needs to participate in



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Q&A

European working time directive

Kendra Inman
The Guardian, Wednesday 22 October 2003

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Government calls for relaxation of Working Time Directive in NHS

Authors: Helen Jaques

Publication date: 30 Jan 2013

In 2003 the BMA intervened in the WTD debate. It was important to hear their opinion.

The issue is back on the agenda, with Cameron calling for relaxation of this. But who will Brussels trust more: A politician or a doctor?

“If you are not at the table, you could be on the menu.”

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Changing landscape in Europe for medical devices – Regulatory standpoint

Medical Technology in Europe

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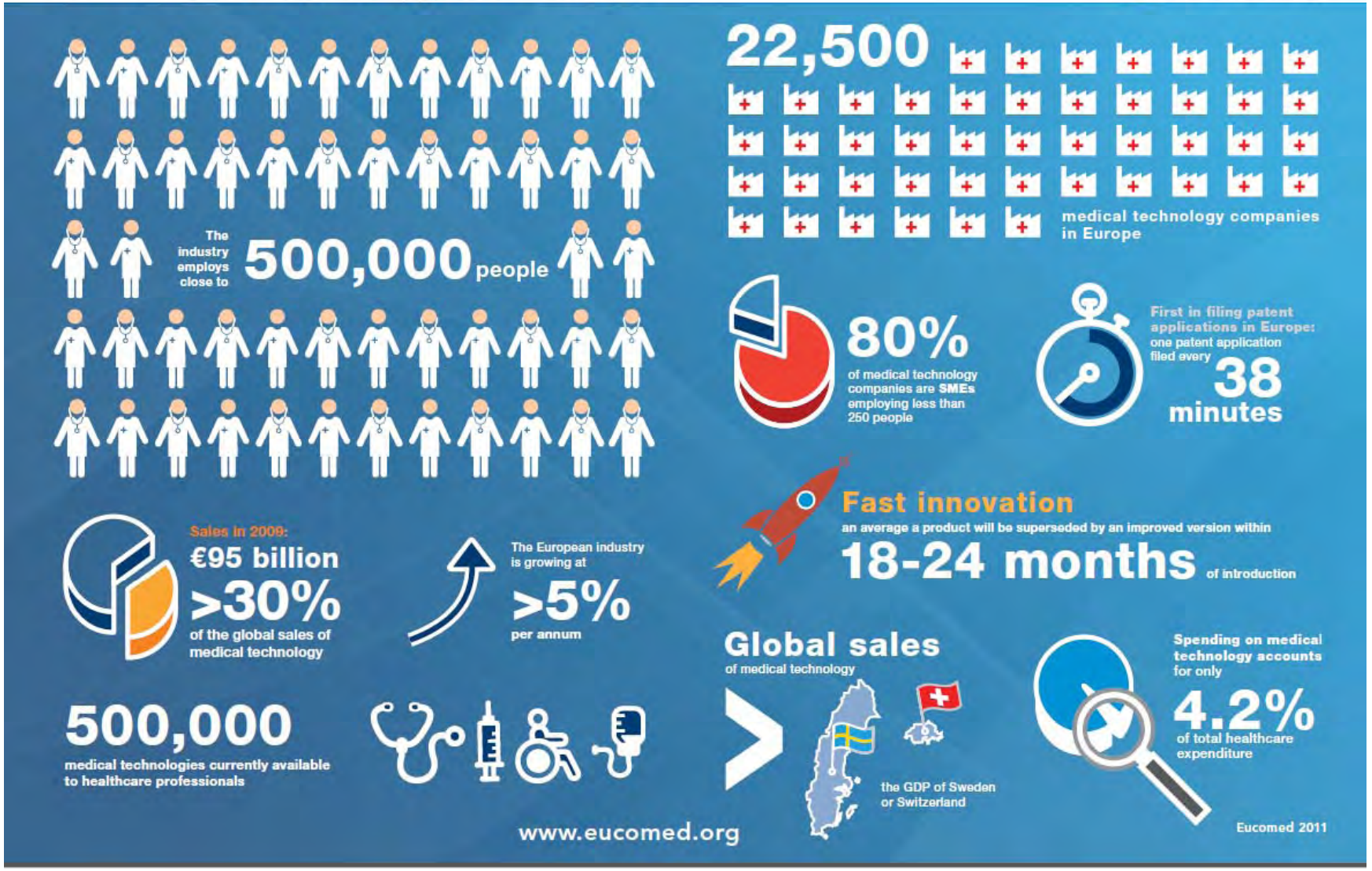

Our Vision on Regulation

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;
- Results in a dynamic environment, which encourages and keeps **research & development and innovation** in Europe.

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the **current** regulatory system

the current regulatory system

keep merits

high level of patient **safety**

availability of latest technology solutions

strong **innovation** capabilities

eliminate weaknesses

fragmentation

regulatory gaps

lack of **transparency**

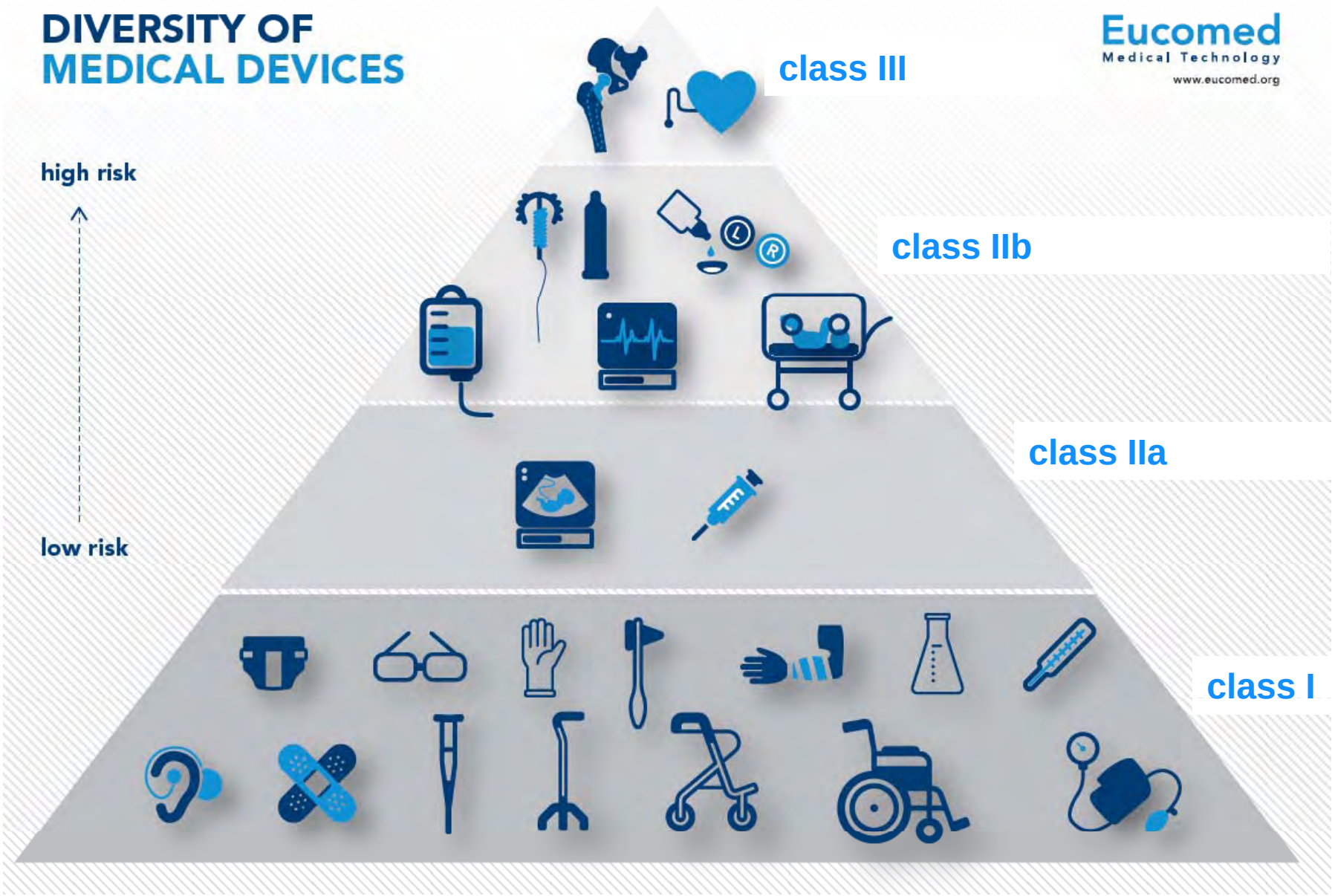
notified bodies

shortcomings in **implementation**

post-market controls functioning

damaged **confidence**

vigilance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high risk
low risk
class III
class IIb
class IIa
class I

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The new proposed Regulation

Which areas will it affect?

How will it improve and guarantee safety?

Eucomed Position on the Revision

- We acknowledge the need for change
- We agree with many measures in the Commission proposal
- 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)?
- **'Scrutiny' & 'PMA' solutions do not meet the 3 criteria – Eucomed opposes !**

the new regulation: improvements

the new regulation: can it go further?

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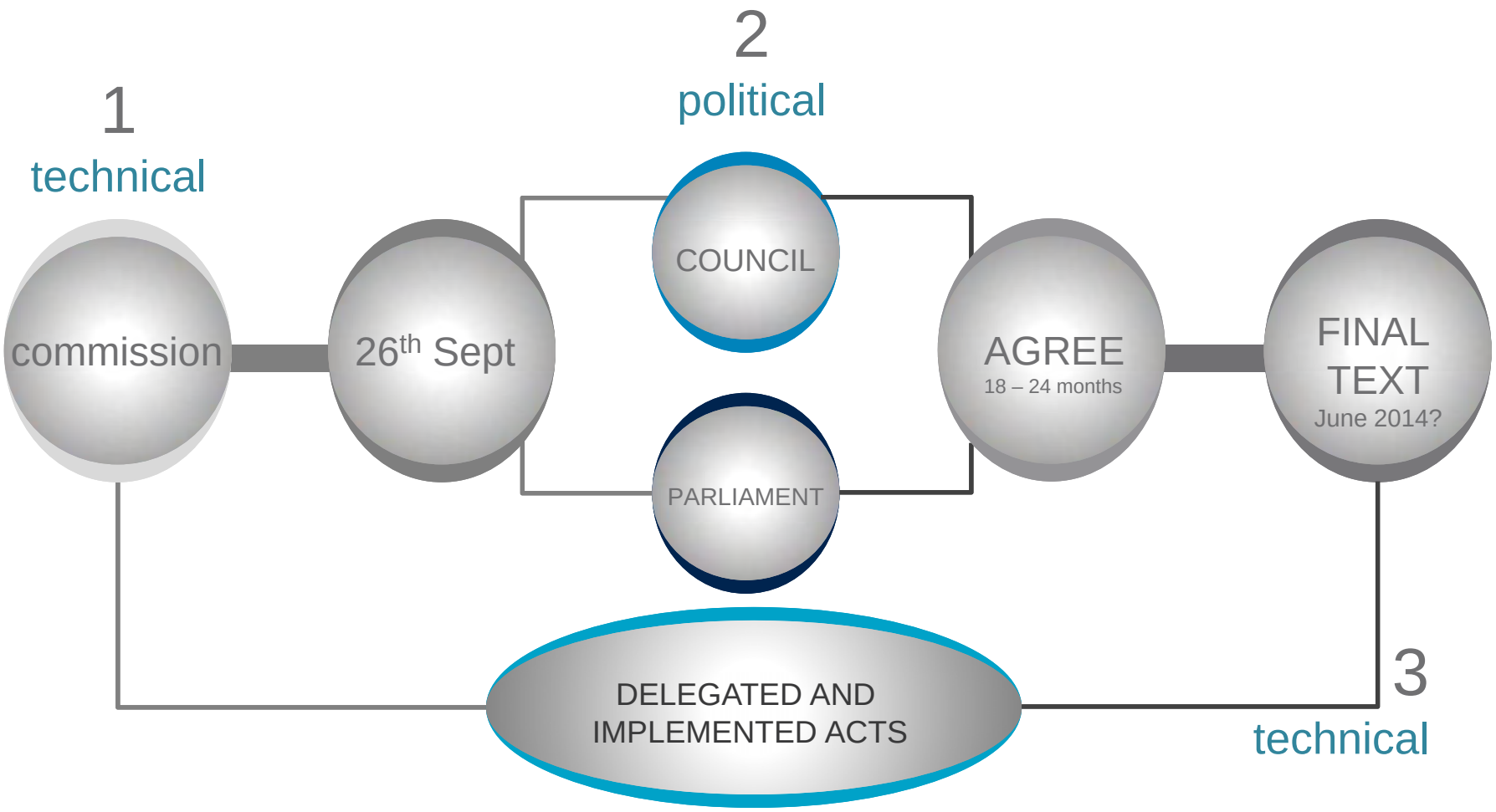
the process : April 2013



Dontloosethe3

Thank You…and to learn more…

DON'T LOSE THE 3

dontlosethe3.eu

http://eucomed.org/key-themes/medical-devices-directives

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