

# Views on the Recast

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# Recast of the Medical Devices Directives

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- ▶ Public consultation (May 2008) and outcome now on Commission's website
  - [http://ec.europa.eu/enterprise/medical\\_devices/consult\\_recast\\_2008\\_en.htm](http://ec.europa.eu/enterprise/medical_devices/consult_recast_2008_en.htm)
- ▶ Proposal late 2009
- ▶ Comes into force 2014? 2015?

# Recast of the Medical Devices Directives

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- ▶ Original Simplification programme of 2005 (to merge texts)
- ▶ European Commission added more major changes due to:
  - Emerging Weaknesses
  - Notified Bodies
  - Vigilance
  - Market Surveillance
  - Transparency
  - New and Emerging Technologies
  - Global Market
  - Greater Simplification and Harmonisation

# Recast of the Medical Devices Directives: Elements of Consultation

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- ▶ Scope
- ▶ New Approach Update
- ▶ Evaluation Procedures
- ▶ Vigilance
- ▶ Market Surveillance
- ▶ Borderline
- ▶ GHTF
- ▶ Imports, Exports & Counterfeiting
- ▶ Simplification

# Recast of the Medical Devices Directives: Elements of Consultation

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# Next Steps

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- ▶ Next Steps - Objectives
- ▶ Beneficial Characteristics of MedTech in Europe
- ▶ Key Messages
- ▶ The areas of special focus:
  - Transparency
  - Notified Bodies
  - Public Authorities

## Next Steps - Objectives

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- ▶ A **strong message** has been sent
- ▶ Now is the time for **productive dialog**
- ▶ **Constructive solutions** that **minimise any negative impact on industry**
- ▶ Solutions must mean **less red-tape** and be **supportive of innovation.**

# Beneficial Characteristics of MedTech in Europe

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- ▶ Proven high level of safety
- ▶ Faster access for European patients to needed technology
- ▶ Current system fosters a high level of innovation and competitiveness
- ▶ SMEs represent a large part of MD industry, nearly 80%
- ▶ Wide range of products and technologies = appropriate rules
- ▶ Short lifecycle of the products = compatible regulatory approval timelines
- ▶ Relatively small (to pharmaceuticals) R&D and Manufacturing costs = compatible regulatory approval costs

# Next Steps - Key Messages

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## ► Key messages

- Eucomed supports the Commission in its efforts to strengthen the system but only insofar as proposed solutions preserve or enhance the known beneficial aspects of the system
- Directive 2007/47/EC and the revised New Approach bring many of the solutions – other tailored solutions may be needed
- Here Eucomed can help the Commission find appropriate solutions

# Next Steps - Key Messages

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## ▶ Key messages

- While all aspects will be tackled, there are some key areas :
  - Notified Bodies
  - Public Authority input or say in the approval of highest risk devices
  - Transparency

## Aim in Key Areas

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- ▶ Notified Bodies Eucomed agrees with the Commission proposals and comes with addition proposals
- ▶ On Public Authority input or say in the approval of highest risk devices Eucomed disagrees with the Commission proposals and proposes other less burdensome and efficient proposals
- ▶ On Transparency, Eucomed proposes measures that bring efficiency, transparency and trust to the system.

# Transparency

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## Transparency (Not a specific item in the consultation)

### Eucomed's message

Greater **transparency** can bring more **efficiency** and **trust** into the framework. The current level of confidentiality and lack of transparency has not helped in **counter-balancing the negative criticism** of the system, particularly in the area of notified bodies

# Transparency

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## Eucomed's proposals

- ▶ Public Eudamed database
- ▶ Central registration
- ▶ Public Summary of safety & effectiveness
- ▶ Listing of notified bodies with details of notification
- ▶ Central reporting of incidents through Eudamed
- ▶ Any CA can ask for NB reports from local CA on specific devices

## Benefits of Eucomed's proposals

- ▶ Trust in system
- ▶ Greater efficiency
- ▶ High level of Transparency and Communication
- ▶ Facilitates checking by all interested parties
- ▶ Promotes internal market
- ▶ Once-off registration cost, eliminating 27 individual registration costs
- ▶ Registration fee can still go to authorities
- ▶ Can help eliminate classification differences
- ▶ Increase patient choice and awareness
- ▶ Decrease likelihood of 27 different vigilance reactions
- ▶ Promotes best practice in Notified Bodies

# Notified bodies

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**Better performance of Notified Bodies** (Items 8 and 12 of the consultation)

## Eucomed's message

The **designation, monitoring and performance of Notified Bodies should be improved** in order to regain the public, industry and third country regulators' trust in their work.

# Notified Bodies

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## Eucomed's proposals

- ▶ In addition to the Commission's proposals Eucomed adds:
  - Restriction of scope of Notified Bodies
  - report on the functioning of Notified Bodies
  - Sectoral Accreditation Standard
  - Accreditation

## Benefits of Eucomed's proposals

- ▶ In line with New Approach
- ▶ Greater transparency
- ▶ Encourages best practice
- ▶ True competence of NBs
- ▶ Encourages 'specialisation' of NBs
- ▶ Use of GMDN
- ▶ Certain Notified Bodies already produce reports.
- ▶ Better for NB competitiveness (costs)
- ▶ Harmonised accreditation standard = same high standard for Notified Bodies
- ▶ Facilitate international alignment
- ▶ Support for Authorities with limited resources (cross-border accreditation possible)

# Notified Bodies

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## Eucomed's proposals continued

- ▶ Agreement by CAs on the designation of NB
- ▶ Assessment of Notified Bodies by CA who may seek expertise at other CA
- ▶ Uniform implementation and enforcement of designation and monitoring/surveillance of Notified Bodies
- ▶ Annual reviews - publicly available
- ▶ Central training and mandatory guidance
- ▶ Advisory Committee, in particular on borderline products
- ▶ and where appropriate Art 7 committee procedure

## Benefits of Eucomed's proposals

- ▶ Competent Authorities have the final 'public health' say on NBs
- ▶ Bring 'public health' into the assessment of Notified Bodies.
- ▶ Strong enforcement = incentive for best practice.
- ▶ Publicly available CA monitoring = best practice, transparency and trust
- ▶ Promotes harmonised practices and interpretations
- ▶ Binding decisions to eliminate non-harmonised interpretations between notified Bodies.

# Authority Involvement

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**Involvement of Competent Authorities in pre-market approval of highest risk devices (Items 9,10 and 11 of the consultation):**

## Eucomed's message

**Competent authorities are already involved** - responsible for the designating and monitoring

**Authorities are also directly involved in the approval of certain high risk class devices**

This current system has:

- **proven history** in providing a **high level of protection of health**
- put **Europe** at the forefront of **innovation**
- ensured a healthy environment for **SMEs - 80%** of manufacturers.

# Authority Involvement

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**Involvement of Competent Authorities in pre-market approval of highest risk devices (Items 9,10 and 11 of the consultation):**

## Eucomed's message

However, Eucomed agrees that a **strengthening of this involvement can resolve the perception** within Europe and outside Europe that authorities are not involved in the approval of medical devices and particularly with high risk medical devices.

This strengthening should be **appropriate and proportionate** and **preserve or enhance the known beneficial aspects** of the system.

# Authority Involvement

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## Eucomed's proposals

Instead of the Commission's proposals Eucomed proposes:

- ▶ To bring strength to the responsibility of the authority in the approval - NB Certificate should mention the following: this certificate is issued by (name of NB) acting on behalf of (country) Ministry of Health.
- ▶ In addition, to bring extra strength to the system, for very specific devices, what can be possible is a TSE/BSE Directive type system with very limited review timeframe (30 days)
- ▶ NB place design examination report on Eudamed, where it can be consulted by all CAs
- ▶ Role of CA in pre-market approval needs to be clearly defined and limited in time:
  - Review of NB assessment report by local CA
  - Review process is limited in time
  - Local CA may consult other CA
  - Procedure restricted to a limited number of devices

# Authority Involvement

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## Specific Devices

- ▶ Not the list the Commission used (stents and pacemakers!!!!)
- ▶ Highest Public Health Interest? (sensitivity)
- ▶ Innovation ≠ High Risk
- ▶ Very limited cases

# Authority Involvement

## Benefits of Eucomed's proposals

Best look at socio-economic impacts:

Aspect	Current Level
Pre-Market Public Authority Input or Say	Low
Level of Bureaucracy	Low
Patient Access	High
SMEs	80%
Approval Costs	€20,000
Approval Timelines	60 - 90 days
Innovation	High
Growth and Jobs	5 - 6% p.a.

# Authority Involvement

## Benefits of Eucomed's proposals

Best look at socio-economic impacts:








Aspect	Current Level	Impact of Commission Proposal
Pre-Market Public Authority Input or Say	Low	High
Level of Bureaucracy	Low	High
Patient Access	High	Medium
SMEs	80%	Reduction
Approval Costs	€20,000	€159,800 to €329,600
Approval Timelines	60 – 90 days	210+ days
Innovation	High	Low
Growth and Jobs	5 – 6% p.a.	< 5%



# Authority Involvement

## Benefits of Eucomed's proposals

Best look at socio-economic impacts:

Aspect	Current Level	Impact of Commission Proposal	Impact of Eucomed Proposal
Pre-Market Public Authority Input or Say	Low	High	 High
Level of Bureaucracy	Low	High	 Low
Patient Access	High	Medium	 High
SMEs	80%	Reduction	 80%
Approval Costs	€20,000	€159,800 to €329,600	 €20,000
Approval Timelines	60 - 90 days	210+ days	 90 - 120 days
Innovation	High	Low	 High
Growth and Jobs	5 - 6% p.a.	< 5%	 5 - 6% p.a.



## Next Steps

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▶ Be **forward looking** and provide **constructive** and **appropriate solutions**

▶ In order to have:

“A **predictable, sustainable** and **appropriate** regulatory environment that supports:

- **Patient Access** to needed technology = **(Growth)**
- **Innovation** and **Competitiveness** = **(Jobs)”**

# Next Steps

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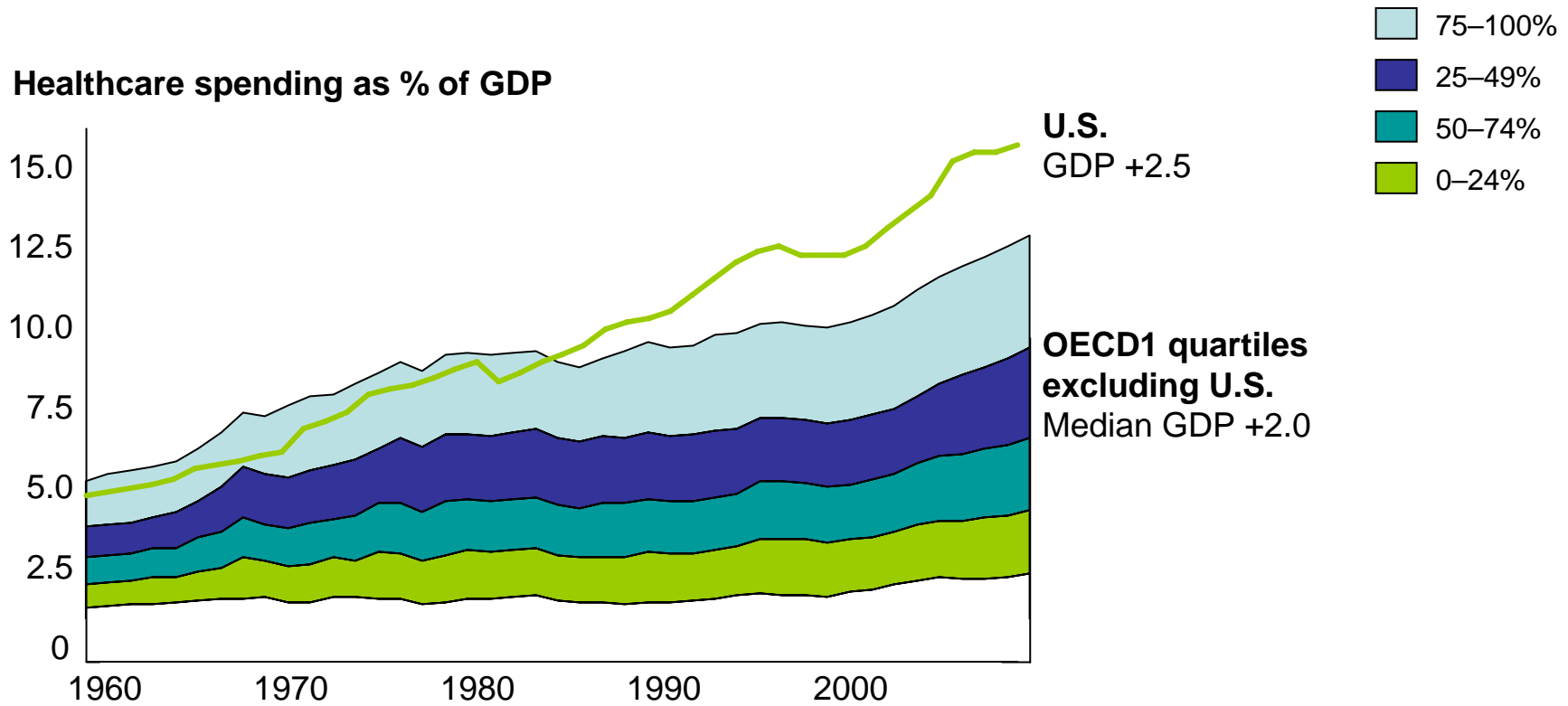
- ▶ Commission is moving too fast and without all the information it needs
  
- ▶ The picture in 15 – 20 years is more difficult and complex than the Commission may be aware

# The fundamental emerging trends shaping the world

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- 1 Shifting centers of economic activity**
  - Emerging markets will account nearly 50% of GDP growth up to 2025
- 2 Growing and ageing population**
  - Over 90% population growth outside OECD – adding 3bn more people (3 times current population of India)
  - Over 240m over 65 yrs in OECD countries in 2025 (vs. 98m in 1980)
  - Median age in Japan >50 by 2025
- 3 Over burdened public sector**
  - Tax increases required to protect benefit levels in 2030
    - Italy 140%
    - Germany 90%
- 4 New consumer**
  - Over 1 billion new consumers by 2015
- 5 Connectivity changing the way we live and interact**
  - E.mail traffic from 40b in 1997 to 8,800b in 2005
  - Double-edged sword
    - Service/experience improves
    - Price transparency creates challenges
- 6 Social costs of the free market**
  - Disenfranchised populations
  - Consumer activation (e.g., starbucksgossip.com)

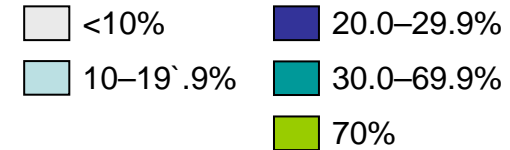
# Health care outstripped GDP over 50 years - with few signs of change



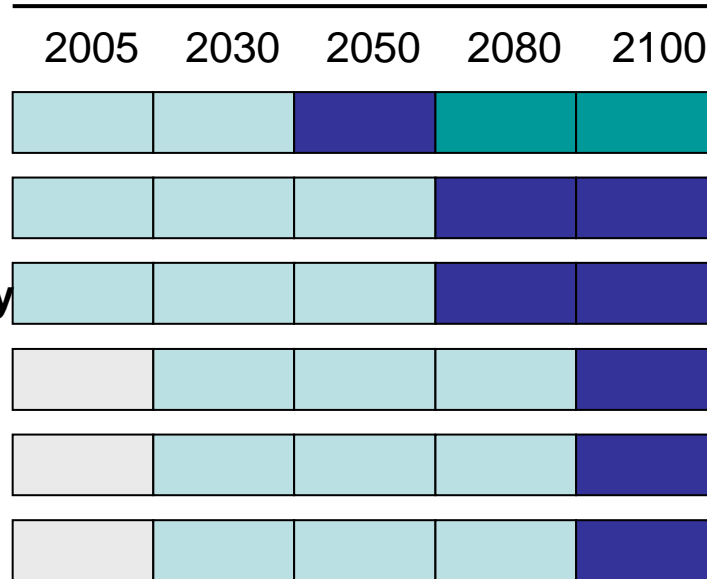
\* Organisation for Economic Co-operation and Development; data reflect fluctuating number of member countries – e.g., 13 countries in 1960, 30 in 2004

Source: OECD; McKinsey analysis

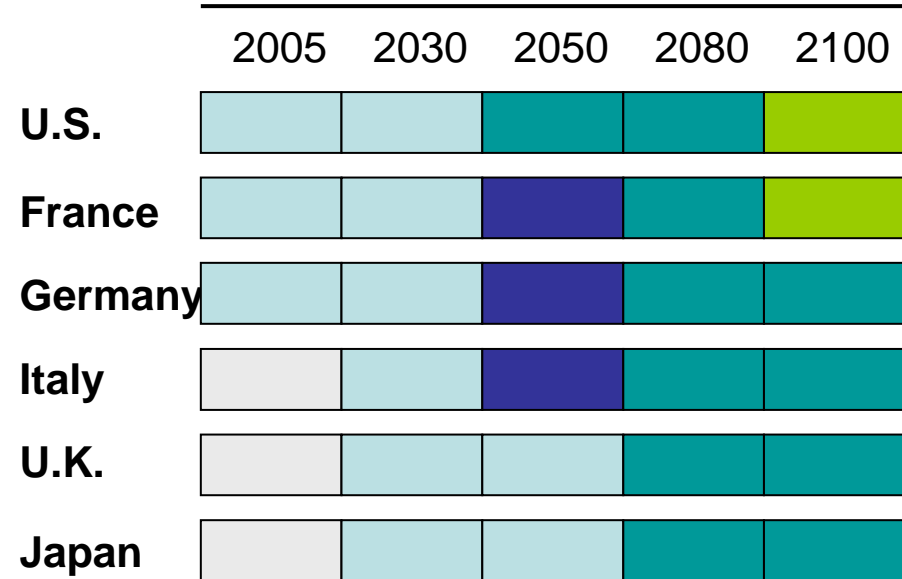
# Scenarios for future spending - 2080



**Half of OECD's1 historic rate: GDP +1%**



**OECD's1 historic rate: GDP +2%**



# Future Challenges

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Complex Products



## Convergent Combination Devices

Con  
Technologies

on

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# Future Challenges

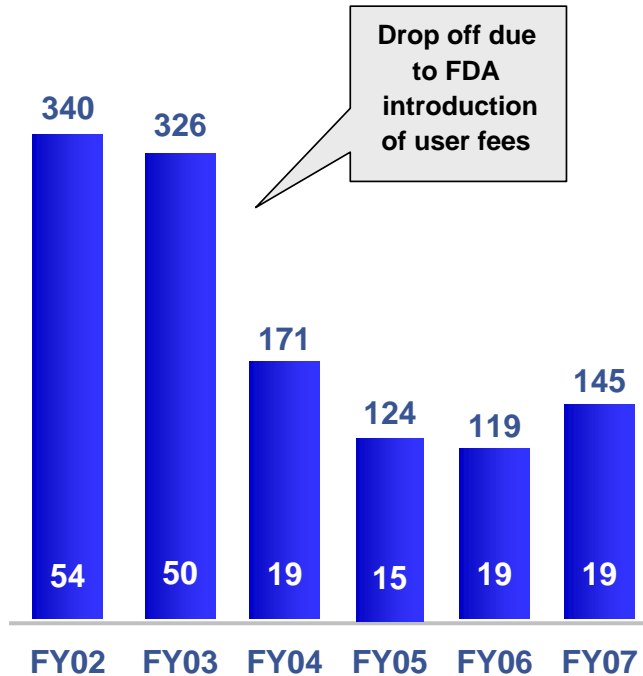
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Bureaucratic thinking can damage innovation

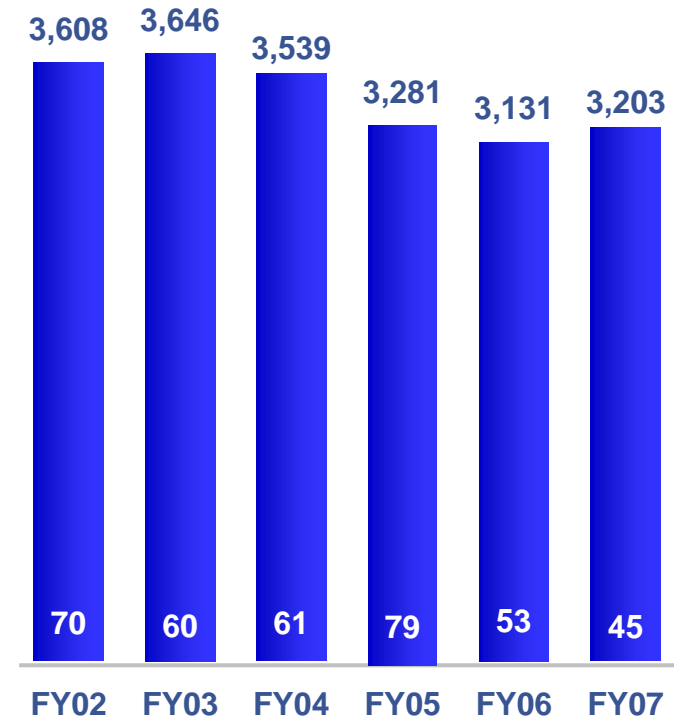
# Future Challenges

## Original PMA plus 180-day Supplements

■ Industry (CDRH applicants)



## 510(k)



# Future Challenges

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- ▶ We need intelligent solutions
- ▶ Innovation is key in tackling future health challenges
- ▶ Current action proposed Commission misses this 'bigger picture'
- ▶ Need better more integrated and broad-reaching solutions for the future

# Future Challenges

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## ▶ 3 Step approach

1. Simplify as originally planned in 2005 (AIMD and MDD merge)
2. We may have already solved a lot of the Commission's problems – take time to analyse impact of Directive 2007/47 and revised New Approach

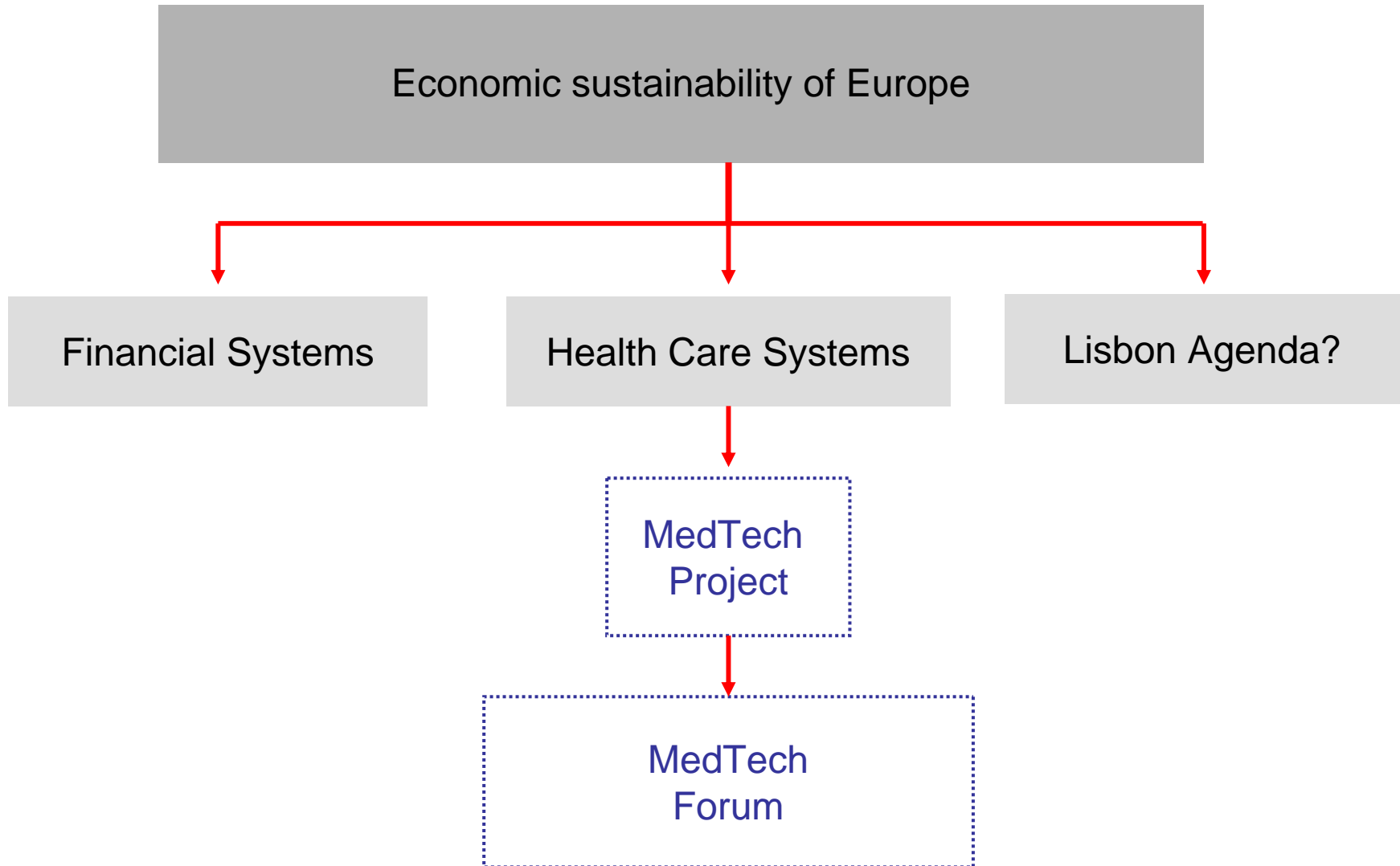
# Future Challenges

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3. Solve the remaining solutions intelligently and together:

- ▶ High level 'Think Tank' to bring real ground-breaking solutions to the future needs of citizens and Governments

# How to preserve sustainability in Europe?



# Primary healthcare goals: Change over time

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Past

Fight illness

Present

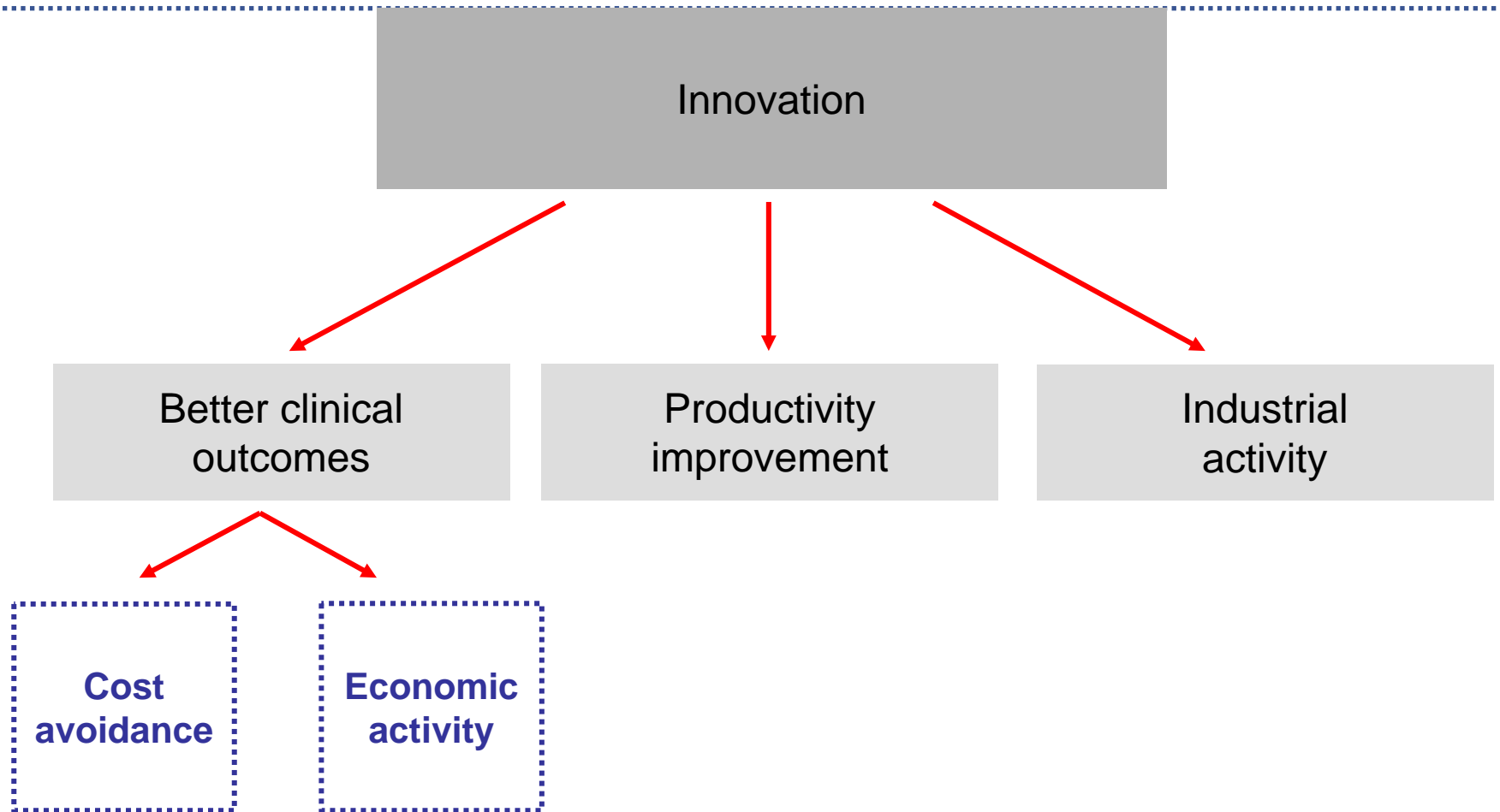
Improve longevity

Future

Add quality to the added years



# Impact of Innovation



## Views on the Recast

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Thank You for Listening

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