Barriers to Innovation in Medical Devices: The Limited Funding of Research & Development

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www.eucomed.org
Eucomed and the Medical Technology Industry

- Eucomed represents the medical technology industry in Europe
  - Eucomed’s mission is to make modern, innovative and reliable medical technology and services available to citizens
  - Members: 25 national associations plus direct corporate members

- Medical technology industry in the EU
  - About 22,500 medical technology companies in EU
  - 80% SMEs
  - €95 billion annual sales; 8% re-invested in R&D
  - Nearly 500,000 employees
  - > 500,000 products (10,000 generic groups)
  - One new European patent every 38 minutes*

*OECD 2010; European Patent Office 2006

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- **The Background**
  - Crisis affecting all sectors
  - Investments in R&D reduced
  - Markets & Revenues flattening

- **The Challenge**
  - Cost of device R&D Increasing
  - Regulatory Hurdles
  - Commoditization & Centralized purchasing
  - Disease progression & Aging

- **The Solution**
  - A Partnership for Innovation – Europe 2020
  - Transform the way to deliver health
  - Medical Technology innovation

https://www.eucomed.org
Health Care Expenditure Evolution

Chart 6: Health expenditure as a share of GDP, EU 27 (% of GDP)

Source: Eurostat.
Chart 4: Full cost of bringing a new chemical or biological entity to market
(US$ m in 2005 dollars)


Eucomed
Medical Technology

www.eucomed.org
Medtech’s long-standing “cycle of innovation” …

Source: Ernst & Young
… now faces new challenges at every stage

- Physicians
- VCs
- Payors
- Big medtech
- Approved technology
- Startup
- CER

- Idea
- Increased transparency requirements
- Pricing pressures
- Buying later
- Device tax, Regulatory hurdles
- Capital crunch

Source: Ernst & Young
Global financial performance:
Non-conglomerates

- **Revenues (US$b)**: +1%
- **Net income (US$b)**: +11%
- **R&D expense (US$b)**: +1%
- **# of employees (000s)**: +2%

Source: Ernst & Young
Key trends in healthcare – The Challenge

- Increase of chronic and multiple diseases
- Increased focus on prevention
- Increasing expectations of citizens
- Shift from public to private funding
- Ageing population & budget constraints
- Increasing e-solutions
- Shift to community and homecare
- Increased demand of medical technology and services
- Increasing role of purchasing & paying institutions
- Declining power of healthcare professionals
The Future of Healthcare in Europe

1. Healthcare spending will continue to raise
2. Universal care will require a degree of rationing and consolidation of Healthcare facilities
3. General practitioners will become more important as gatekeepers & coordinators of treatment in patients with multiple health issues
4. Preventive measures will become more important as a way of promoting healthy behavior
5. European Governments will need to find a way to improve collection and transparency of health data in order to prioritize investment decisions
6. Patients will take more responsibility in their own health, treatment & Care
7. Governments will have to tackle bureaucracy and liberalise rules that restrict the roles of Healthcare Professionals & artificially raise the cost of medical research
Europe’s Debt Mountain

European Sovereigns’ Increasing Net General Government Debt

Note: Gross government debt net of liquid government assets. Assets acquired as part of financial sector support measures have not been considered. Austria: Including debt of infrastructure companies Asfinag and OeBB-Infrastruktur Bau AG. France: Including the debt of Reseau Ferre de France, not including the debt of Societe de Financement de L’Economie Francaise. f—Forecast. © Standard & Poor’s 2009.
Aging will particularly hit Europe
Population Development for Selected Countries (2050)

Switzerland: 2050
Source: U.S. Census Bureau, International Data Base.

Germany: 2050
Source: U.S. Census Bureau, International Data Base.

France: 2050
Source: U.S. Census Bureau, International Data Base.

India: 2050
Source: U.S. Census Bureau, International Data Base.
The Solution

Outlook: rules of the road
## Rules of the road

<table>
<thead>
<tr>
<th>Demonstrate value proactively</th>
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<td>- Identify products most at risk and consider conducting own CER</td>
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<td>- Define appropriate value measures &amp; build processes to capture key data</td>
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<td>- Increase product attractiveness through new pricing models or offering different combo features</td>
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<table>
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<th>Innovate innovation</th>
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<tr>
<td>- “Whittle-down” innovation</td>
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<td>- “Trickle-up” innovation</td>
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<td>- “Pick your size” innovation</td>
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<th>Collaborate</th>
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<td>- Increase reliance on strategic alliances – some with non-traditional partners</td>
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<td>- Develop specialized functional capabilities and skill sets</td>
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<td>- Go global</td>
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<th>Preserve the ecosystem</th>
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<td>- Emerging medtechs must creatively search for alternative funding options</td>
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<td>- With emerging companies struggling, large firms could invest in undervalued assets via venture arms or incubators</td>
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Driving efficiencies through MedTech innovation

- Medical device spending accounts for 2-5% of total healthcare spending
  - cost saving in medical devices has limited impact

- Operational expenses reach ~80-85% of total spending
  - small change here: significant impact

| Source: Espicom; WHO; World Bank, LEK analysis |

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<tr>
<th>Devices</th>
<th>Pharmaceuticals</th>
<th>Operating and other costs</th>
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<td>5%</td>
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Devices spending as a % of total healthcare spending:

- Sweden
- US
- UK
- Taiwan
- Germany
- Singapore
- Canada
- Hong Kong
- Norway
- China
Optimal Healthcare Management

1) Address EU top priorities: Active and healthy ageing and the Innovation Union

2) Capitalize on the MedTech industry to provide solutions for sustainable healthcare systems

3) Develop smart systems (regulatory, procurement, HTA and funding) that incentivise innovation
EU’s innovation policy

- "Innovation Union" - one of the seven Europe 2020 flagship initiatives
- **Ambition**: creating an Innovation Union by 2020 through significantly improved R&D funding and better support of research and innovation until market success
- **34 individual actions** in 7 main areas such as knowledge base, getting ideas to market and European Innovation Partnerships
- significantly strengthened **governance** (national self-assessments of national innovation policies; development of an innovation indicator; new Innovation Council)
What does innovation in Medical Technology deliver?

1) Contributing to active & healthy life years of people and maintaining their productivity

2) Driving efficiencies of healthcare systems

3) Addressing overburdening and shortage of healthcare workers and carers

4) Reducing the variations of impact of the human factor on health outcomes
Incentivising innovation: Future scenarios

**LIMITED INNOVATION**

*System:* complex, expensive  
*SMEs:* survive; high barriers for entry  
*Healthcare:* limited patient choice

**LOW INNOVATION**

*Systems:* price as only driver  
*SMEs:* Highly pressured; ‘size matters’  
*Healthcare:* Basic care for many people; no patient choice

**VALUE driven**

**OPTIMAL INNOVATION**

*System:* incentivising innovation; high collaboration of all players;  
*SMEs:* flourish; high competition  
*Healthcare:* Diverse needed solutions for care; huge patient choice

**MARKET DRIVEN**

**HIGHLY REGULATED**
Implication for future healthcare management

DO MORE WITH LESS!

High level of healthcare vs. Higher demand and same/less budget

Need for new healthcare management models!

1. Addressing the entire patient pathway
2. Integrating patient as an active player
3. Overcoming silo-budgeting and silo-management of healthcare
Getting ready for the future

We need a SAFE, SMART and SUSTAINABLE legislative FRAMEWORK for the MedTech industry, because

- Medical technology allows people to live healthier, more productive and independent lives and is a critical and integral part of an holistic approach to patient care

- Medical technology lowers health care costs and improves quality and efficiency of care

- Medical technology industry is a driver of European growth and jobs through innovation
Conclusions

- The Medical Technology sector is one of the most innovators, improving and saving lives
- Patient-centered Healthcare Systems ensuring early access to innovative technologies
- Harmonization of Best Practices & Guidelines to ensure optimal healthcare
- Sustainable Funding & Reimbursement
- Fast market access for innovation
“They always say time changes things,
But you actually have to change them yourself.”

Andy Warhol, *The Philosophy of Andy Warhol*