

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

Jose Calle Gordo
Chairman Cardiovascular Sector Eucomed
Divisional Vice President EMEA & CALA Abbott Vascular

Medical Innovation in Arrhythmias. The expectation, The Barriers, The developments. 21-22 March 2011
European Heart Hease – Nice, France

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*





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

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



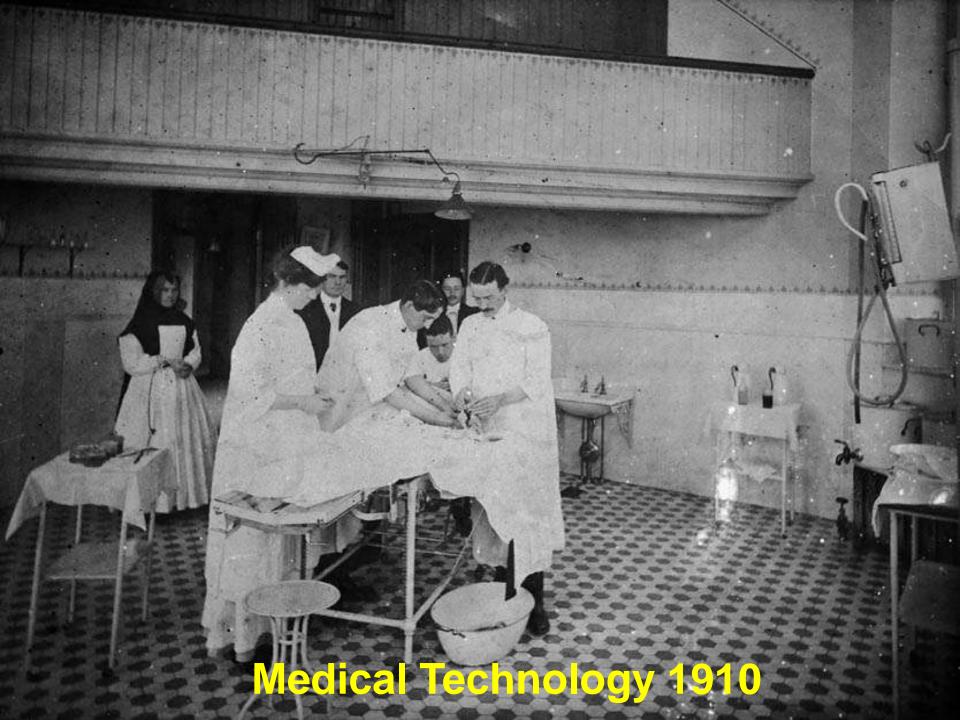








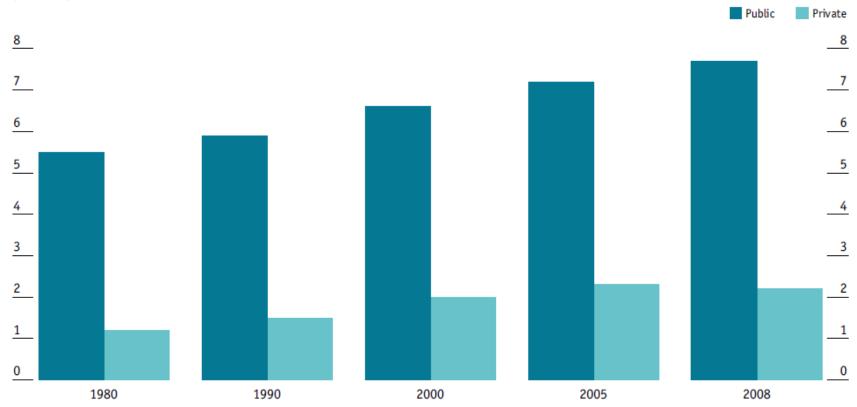






Health Care Expenditure Evolution

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

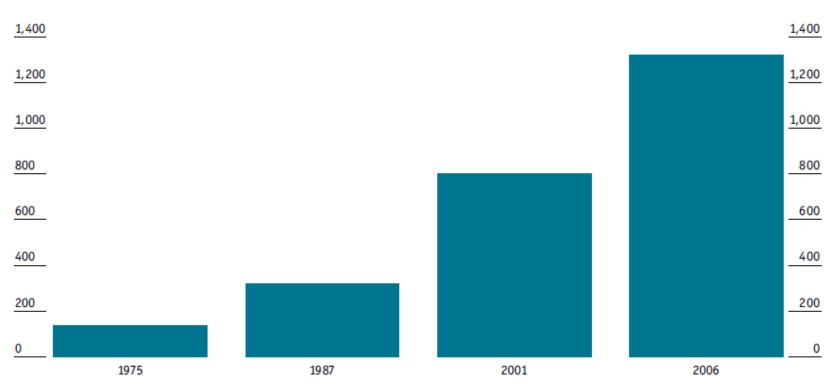


Source: Eurostat.



Cost of Developing Innovation

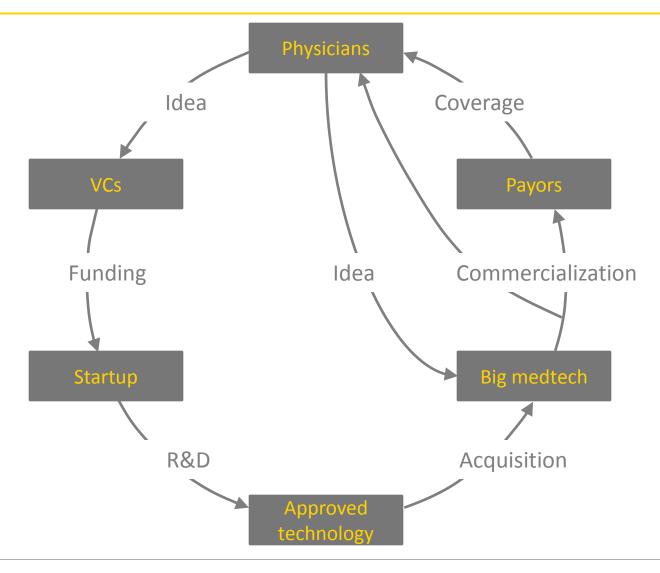
Chart 4: Full cost of bringing a new chemical or biological entity to market (US\$ m in 2005 dollars)



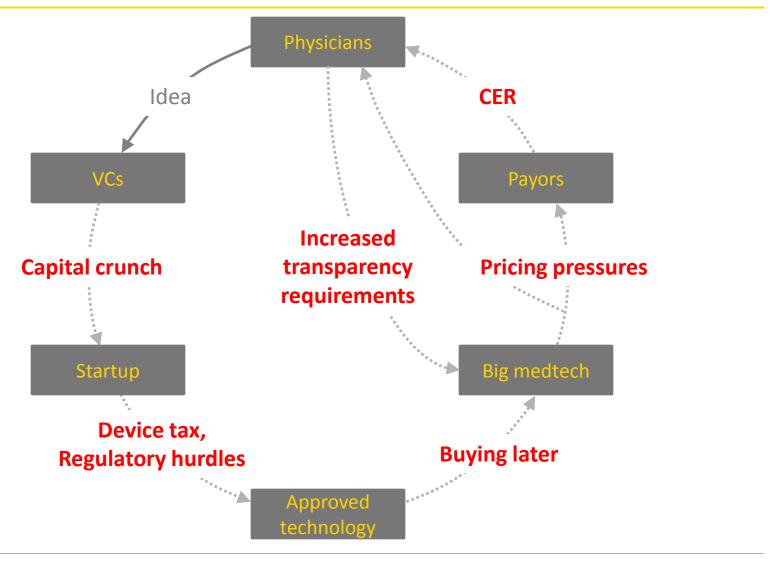
Sources: J.A. DiMasi and H.G. Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?" Managerial and Decision Economics 28 (2007), pp. 469-479



Medtech's long-standing "cycle of innovation" ...



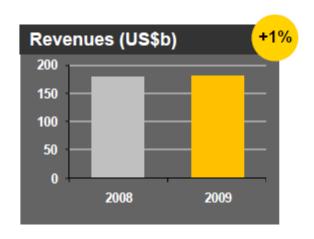
... now faces new challenges at every stage

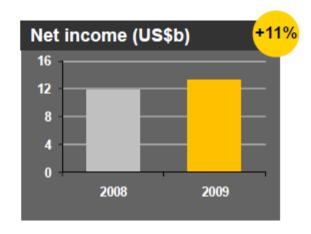


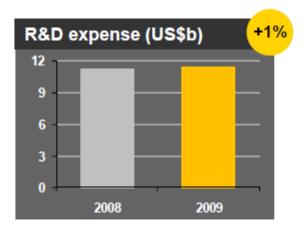


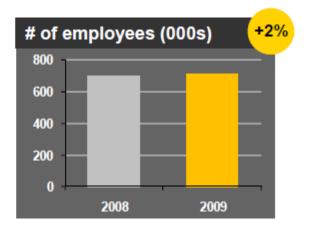
Global financial performance:

Non-conglomerates









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
- 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
- Governments will have to tackle bureaucracy and liberalise rules that restrict the roles of Healthcare Professionals & artificially rais the cost of medical research

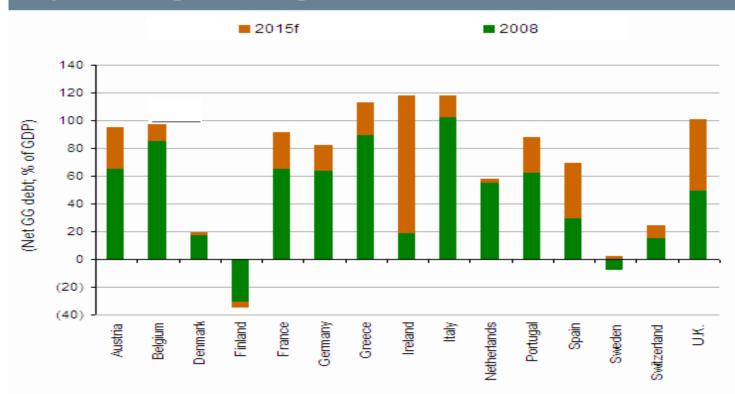






Europe's Debt Mountain

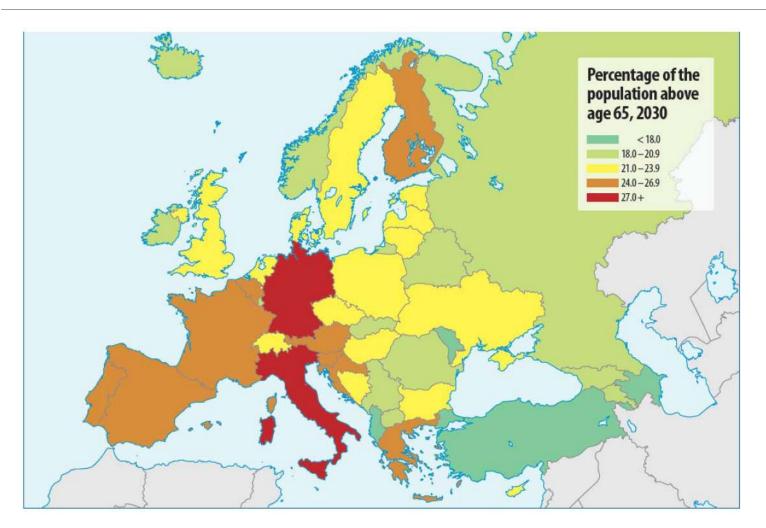
European Sovereigns' Increasing Net General Government Debt



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.

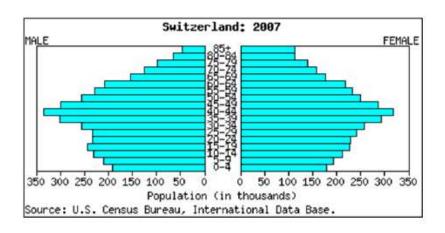


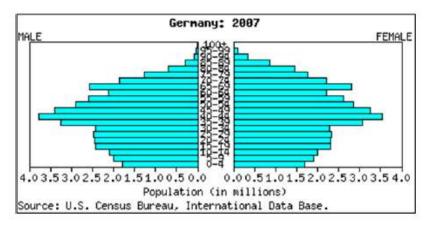
Aging will particularly hit Europe

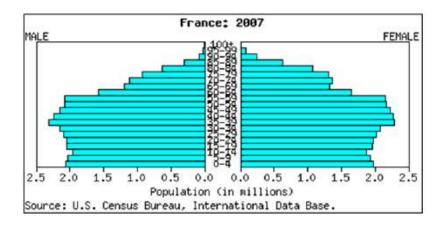


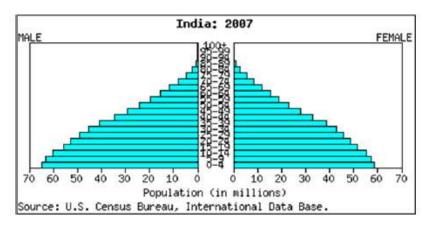


Population Development for Selected Countries (2007)





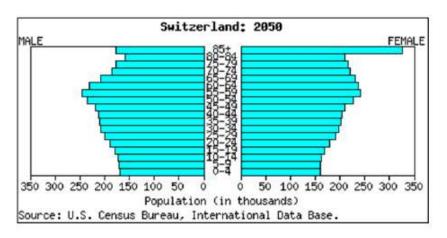


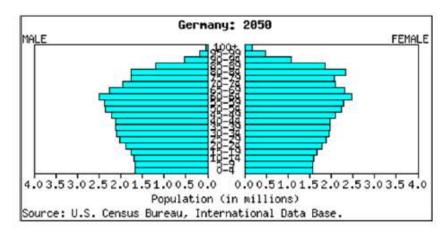


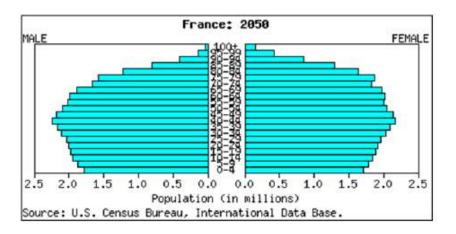


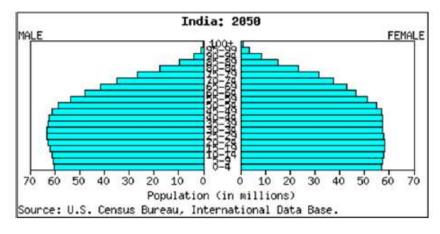
Quelle: U.S. Census Bureau

Population Development for Selected Countries (2050)











The Solution

Outlook: rules of the road



Rules of the road

Demonstrate value proactively

- Identify products most at risk and consider conducting own CER
- Define appropriate value measures & build processes to capture key data
- Increase product attractiveness through new pricing models or offering different combo features

Collaborate

- Increase reliance on strategic alliances – some with nontraditional partners
- Develop specialized functional capabilities and skill sets
- Go global

Innovate innovation

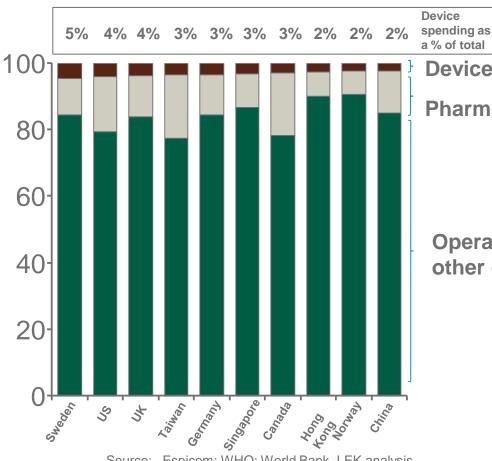
- "Whittle-down" innovation
- "Trickle-up" innovation
- "Pick your size" innovation

Preserve the ecosystem

- Emerging medtechs must creatively search for alternative funding options
- With emerging companies struggling, large firms could invest in undervalued assets via venture arms or incubators

Driving efficiencies through MedTech innovation

(%, 2008)



Devices

Pharmaceuticals

Medical device spending accounts for 2-5% of total healthcare spending

cost saving in medical devices has limited impact

Operating and other costs

> Operational expenses reach ~80-85% of total spending



small change here: significant impact

Source: Espicom; WHO; World Bank, LEK analysis



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
- 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

VALUE driven

LIMITED INNOVATION

System: complex, expensive SMEs: survive; high barriers for entry

Healthcare: limited patient

choice

HIGHLY REGULATED

LOW INNOVATION

Systems: price as only driver SMEs: Highly pressured; 'size

matters'

Healthcare: Basic care for many

people; no patient choice

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





COST driven

www.eucomed.org

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



