



Commercialising Medical Technology The Market and Regulation



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Medical Technology Sector

**2,771 companies in UK generating £10.6bn of turnover
52,000 people mostly in small and medium size enterprises**

**UK pharmaceutical = 67,000 people working
in 596 enterprises and turnover of over £16bn**

**£150-170bn worldwide growing at 10% per annum
the market size will approach £300bn by 2015**


(Office of Life Science - December 2009)



Commercialising Medical Devices
A Guide for UK Based Small Companies

Quotec Ltd

June 2009

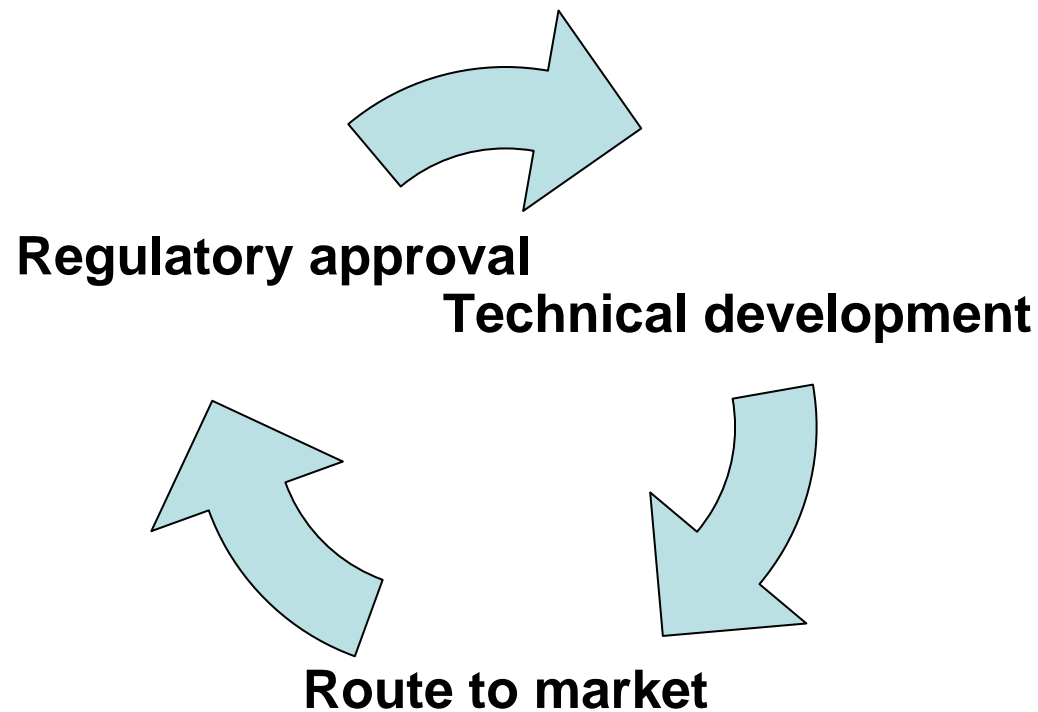

National Institute for
Health Research



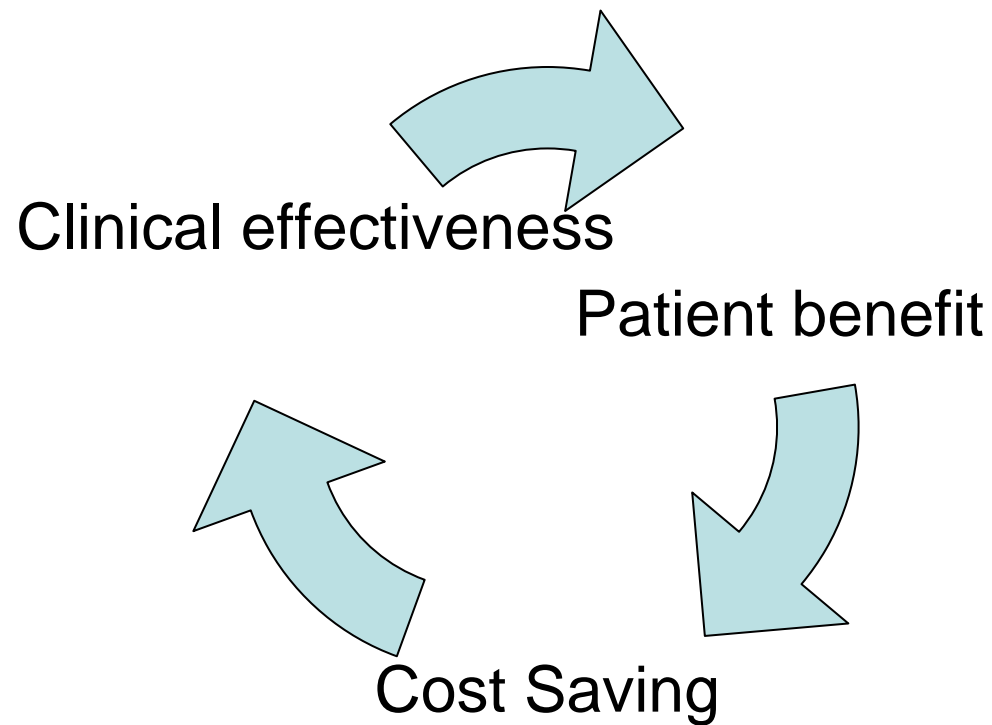
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Key Issues in Medical Device Development



Key Issues in Medical Device Development



Markets

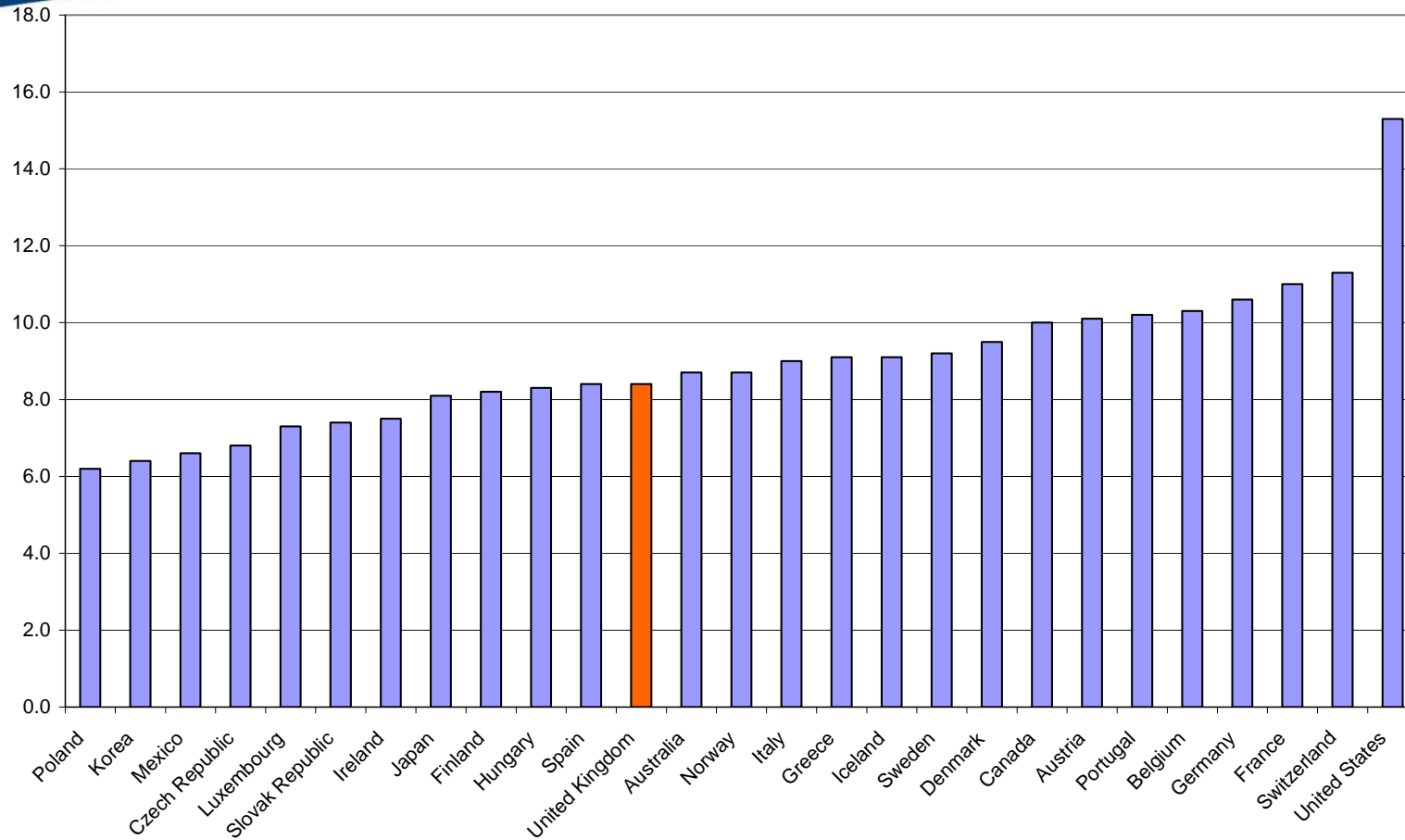


Figure 1: Healthcare Expenditure in OECD countries (2006 as % of GDP)

Markets

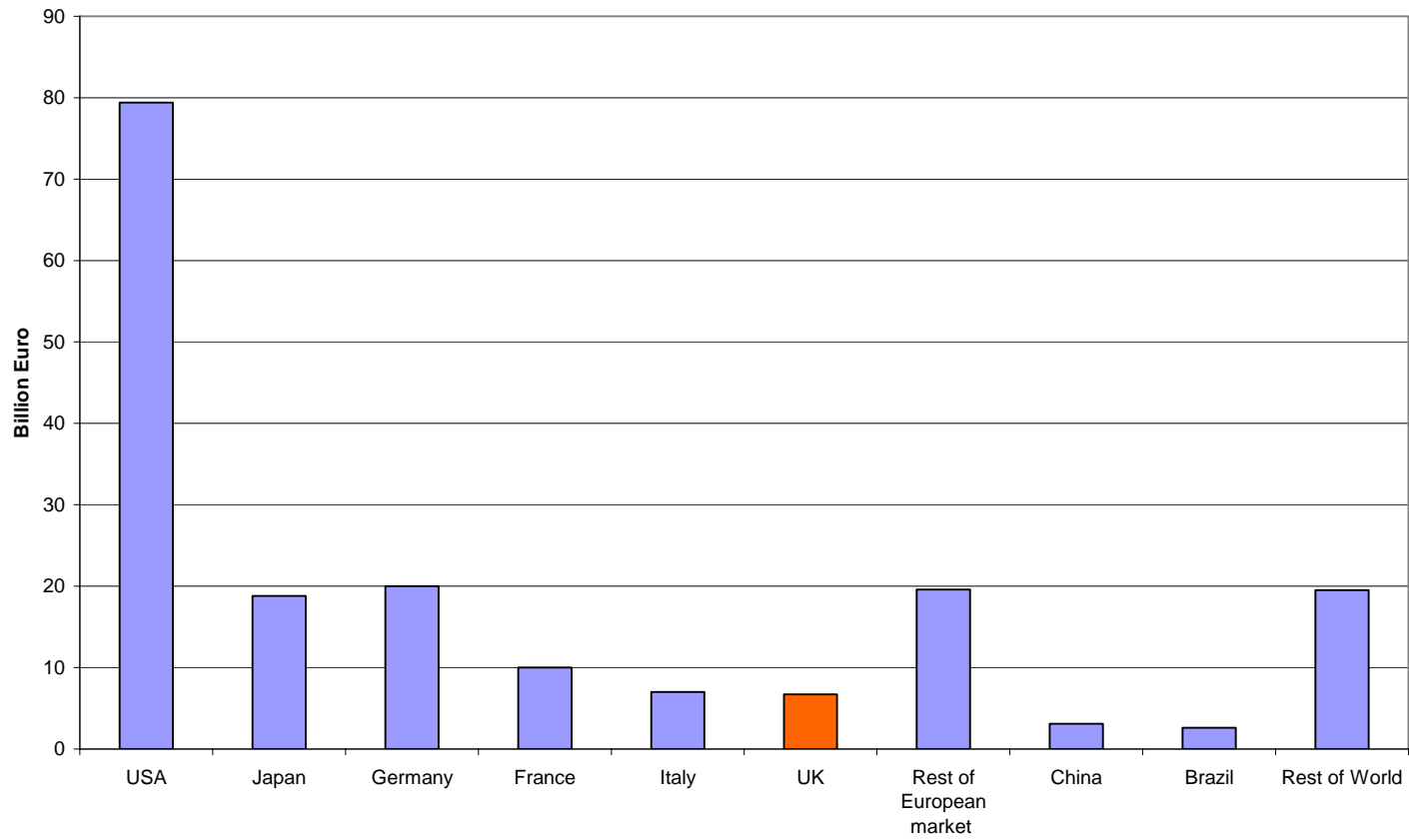


Figure 2 The World Market for Medical Devices (2005)

Market trends/drivers

Ageing Population

- **cost, automation, telemedicine,**

Empowered Patient

- **Knowledge, financial muscle, safety concerns/expectations**

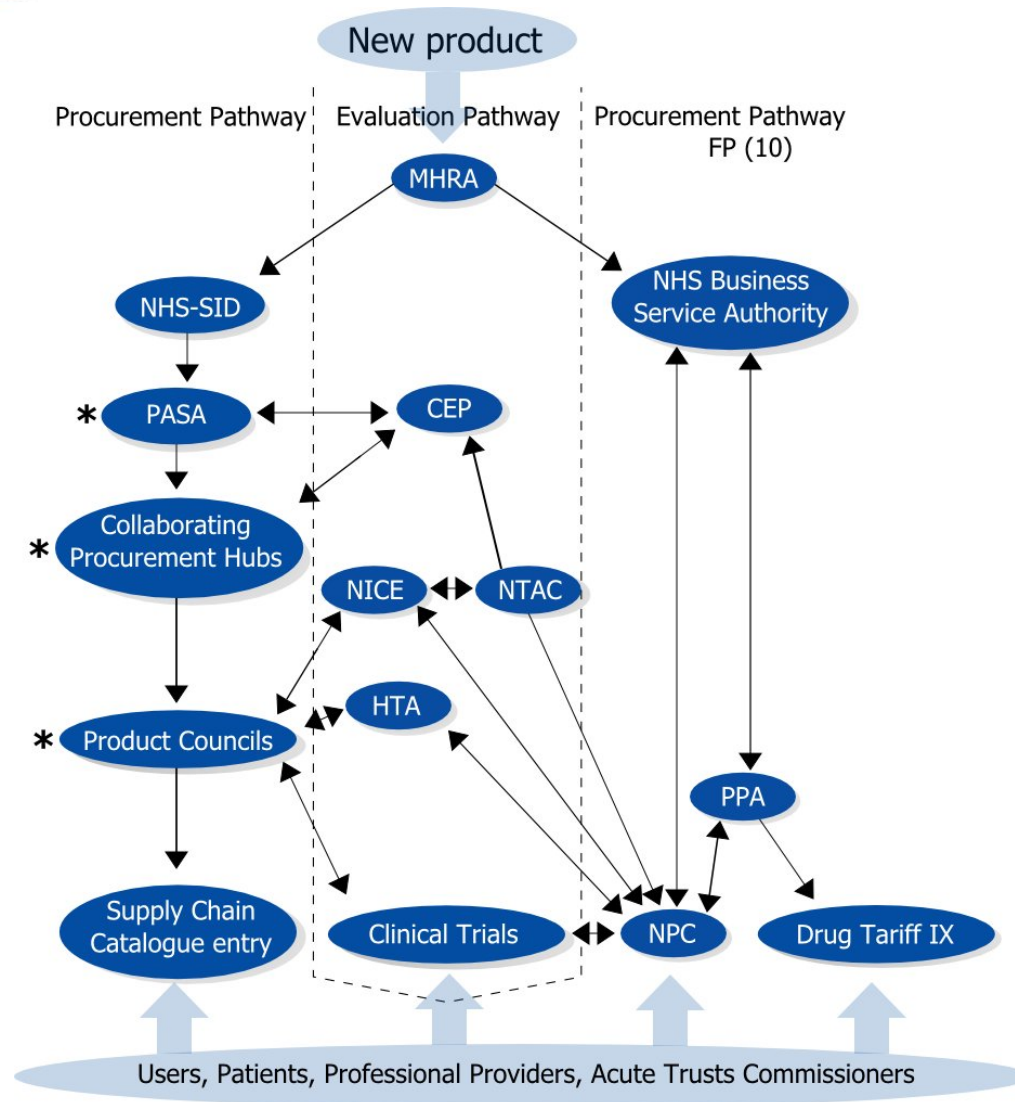
Cost containment

- **reduced hospital stays, primary care, diagnostics, retail services**

Technology

- **robotics, telemedicine, imaging, bio-actives, mass customisation**

Procurement Processes UK NHS



Procurement Processes US

Insurance based reimbursement

CPT Code essential

FDA approval essential

UK Regulation

EU Medical Device Directive

UK Medicine and Healthcare Products Regulatory Agency (MHRA)

assessment and approval prior to CE Marking

Tests dependent on classification level

Primarily concerned with safety

US Regulation

**Food and Drug Administration FDA
Centre for Device and Radiological Health**

**Requirement for safety and efficacy
Regulated by class of device**

Common Problem Areas

1. **Need to understand the market need, competition and competitor reaction**
2. **Need to seek early advice on regulation and market development**
3. **Direct sales is not the only route to market**
4. **Research is only a small market**
5. **Pricing is still important – link to benefit**
6. **Ensure adequate team experience across technology, commerce/production and sales**
7. **IP poorly protected**
8. **Needs of investors not understood**
9. **Over-engineering or over-specification**
10. **Lack of USP**

Other Information

www.quotec.co.uk/resources.htm

Email enquiries@quotec.co.uk