

A large, stylized letter 'S' composed of two thick, curved lines. The top curve is green and the bottom curve is blue, with the two curves overlapping in the center.

EIT Health  
**Summit**

L  N D  N 2  1 7

# Reimbursement in Europe

Tues 5<sup>th</sup> Dec  
11.00am

# Overview of Session



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11.00	Introduction to Reimbursement In Europe Session	James Rose
11.15	The EU Health MAPPS Project	Erwin Heeneman
11.30	Supporting start-ups & SMEs in expanding their markets (Go Global MedTech Accelerator)	Joerg Trinkwalter
11.45	CRAASH: EIT Health Moebio Bootcamp	Raquel Riera
12.00	Panel Discussion and Q & A	All
12.30	Session close	

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# Introduction to Reimbursement in Europe

Dr James Rose  
Oxford AHSN

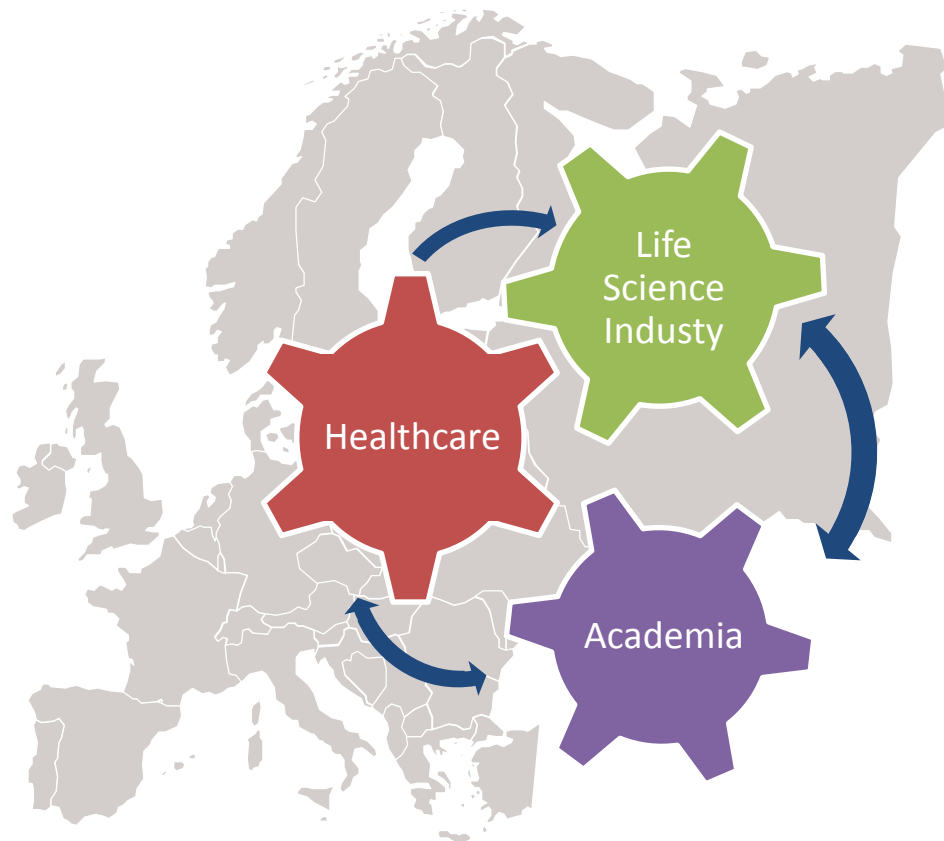
# Trends in European Healthcare



-  Ageing population
-  Escalating burden of chronic disease
-  Increased expectation of healthcare
-  Ballooning healthcare expenditure



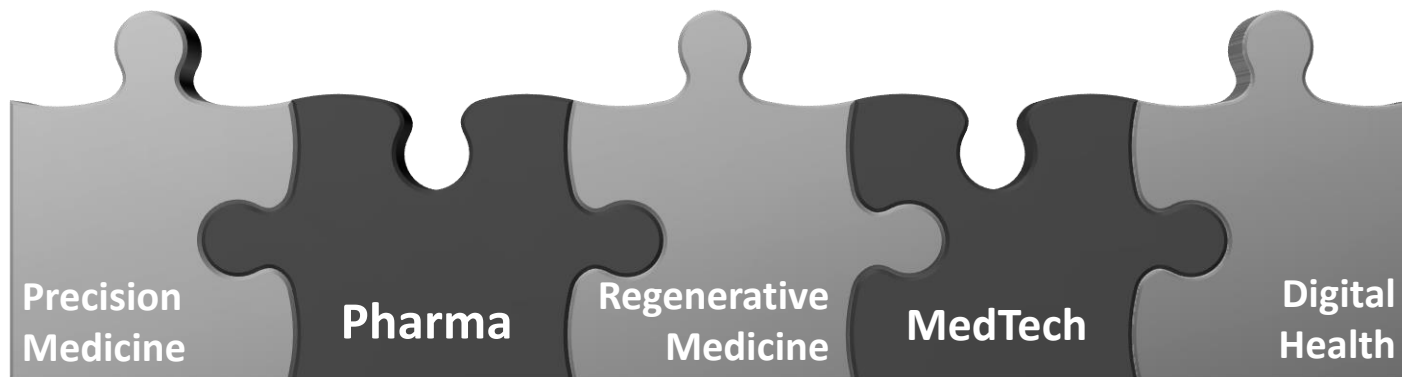
# Trends in European Healthcare



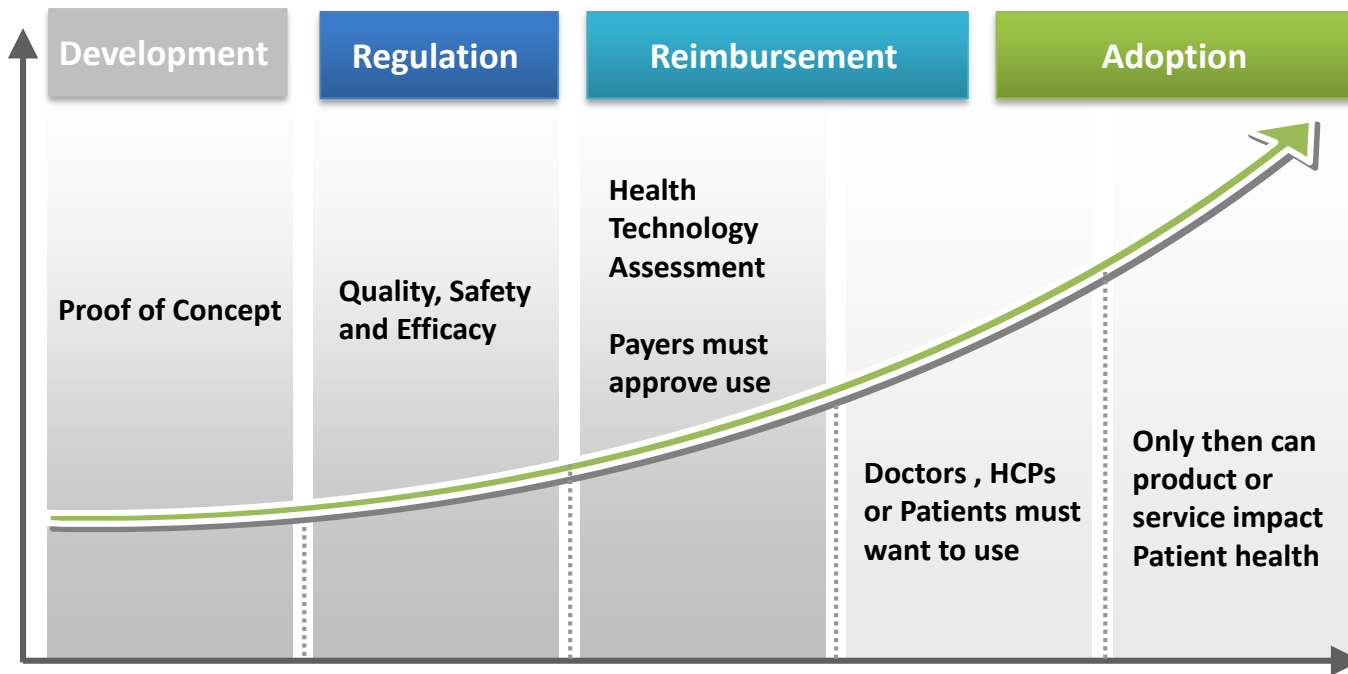
Healthcare leaders are looking to **innovators** for support in reshaping healthcare

- Improved Outcomes
- Improved Efficiency
- Reduced Cost

# Emerging sectors expected to provide part of the answer



# A long and expensive journey for SMEs





# Regulatory processes harmonised across EU

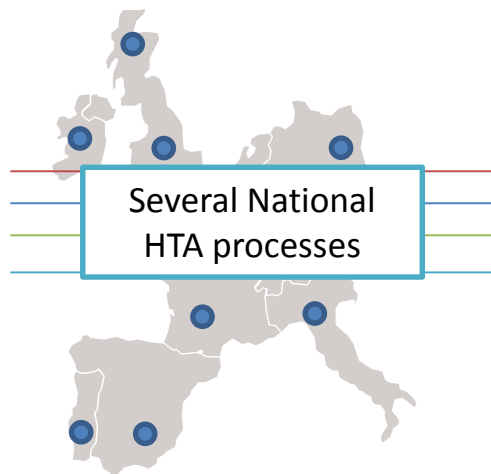
## Regulation



- **Medicines:** EU wide requirements around quality, safety, and efficacy
- **Med Tech:** Directives replaced by Medical Device Regulations
- **Data:** Directives being replaced by GDPR

# Reimbursement handled at Member State level

## Reimbursement



- HTA agencies each with **different:**
  - **decision criteria**
  - **processes**
  - **timelines**
  - **submission requirements**

Scottish  
Medicines  
Consortium

TLV

**NICE** National Institute for  
Health and Care Excellence








IQWiG

**HAS**  
HAUTE AUTORITÉ DE SANTÉ

  
*Agenzia Italiana del Farmaco*  
**AIFA**



# Divergence in decision making criteria

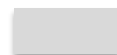
Outcomes					
Clinical Effectiveness	Key Requirement	Key Requirement	Key Requirement	Key Requirement	Key Requirement
Cost Effectiveness	Key Requirement	Not required	Not required	Not required	Key Requirement
Budget Impact	Key Requirement	Key Requirement	Key Requirement	Key Requirement	Key Requirement
HRQoL	Key Requirement	Nice to Have	Nice to Have	Nice to Have	Nice to Have
SOC Comparators	Key Requirement	Key Requirement	Key Requirement	Key Requirement	Key Requirement
Real World Data	Nice to Have	Nice to Have	Nice to Have	Nice to Have	Nice to Have
Innovation	Nice to Have	Key Requirement	Nice to Have	Key Requirement	Nice to Have



Key Requirement



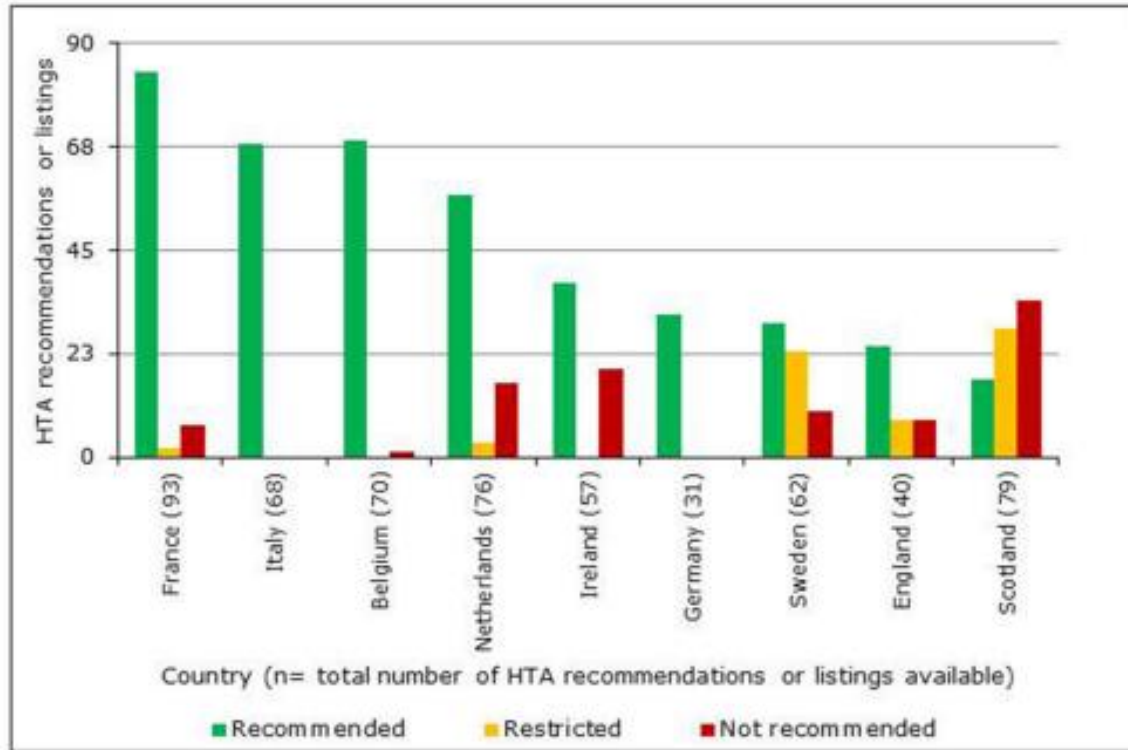
Nice to Have








Not required



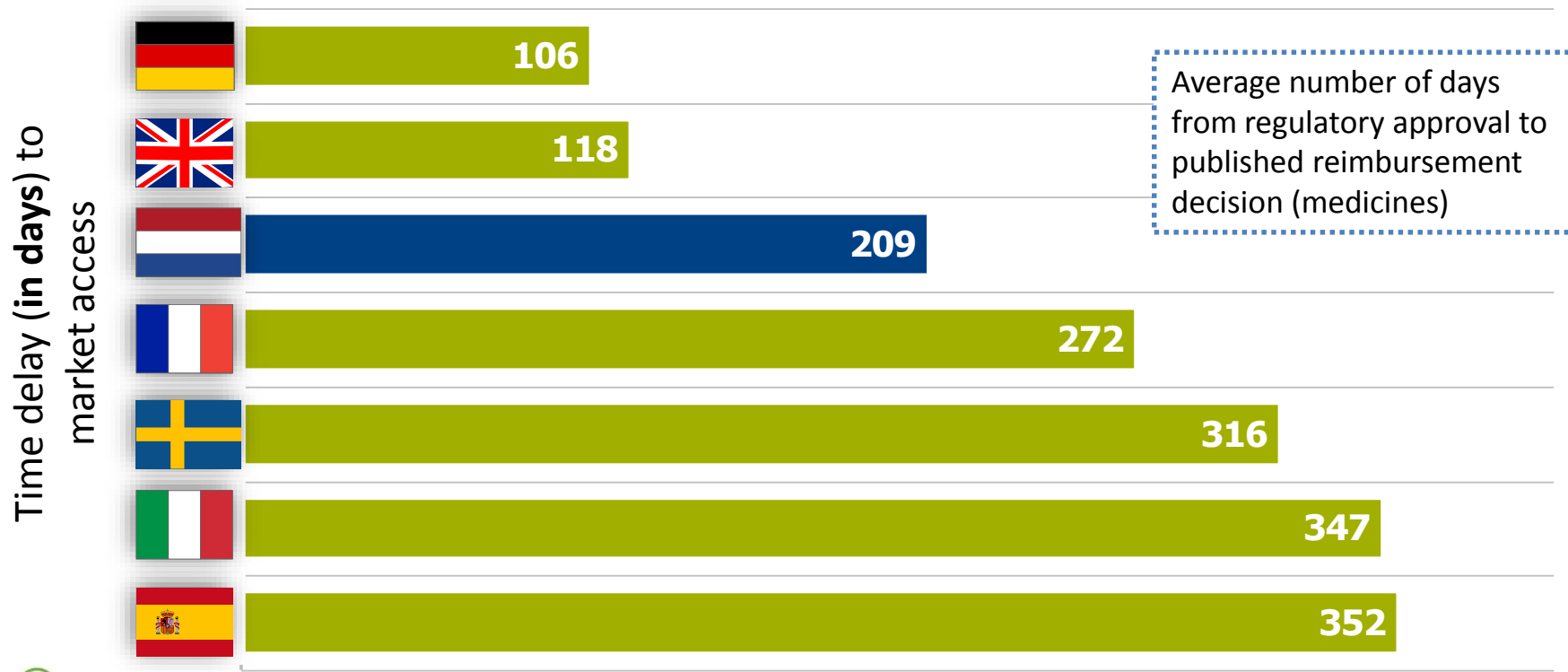
# Variations in capacity and decisions on value



# Same dataset results in different decisions

					
<b>Crizotinib (Xalkori)</b> non-small cell lung cancer	Rejected	Reimbursed (ASMR III)	Added Benefit not proven	Approved with conditions	Reimbursed with conditions
<b>Eribulin (Halaven)</b> metastatic breast cancer	Rejected	Approved with restrictions (ASMR IV)	Added Benefit not proven	Approved with conditions	No recommendation
<b>Ipilimumab (Yervoy®)</b> advanced melanoma	Approved with PAS	Approved (ASMR III)	Added Benefit	Approved	Rejected

# Delays to Reimbursement decisions vary



## Medicines



### **Early Access to Medicines Scheme**

- Rapid access to patients
- Not reimbursed
- Potentially prioritised HTA
- Accelerated mandate for commissioning



### **Temporary Authorization for Use (ATU)**

- Product reimbursed at manufacturers price
- HTA after ATU period
- Reimbursement decision based on SMR
- Price renegotiated on ASMR rating



## Medical Devices



### **NUB Payments**

- Significant lead time to establish new code
- Hospitals apply for reimbursement during that period



### **Innovation and Technology Tariff / Payment**

- Innovative medical devices and digital tech
- Can lead to complete system wide reimbursement
- Support in spread across England from AHSNs

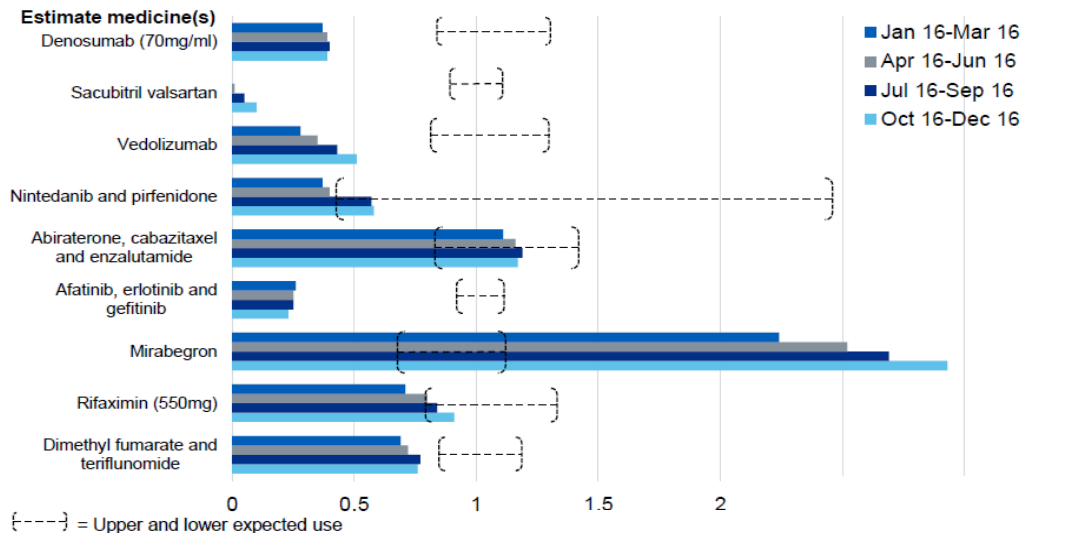
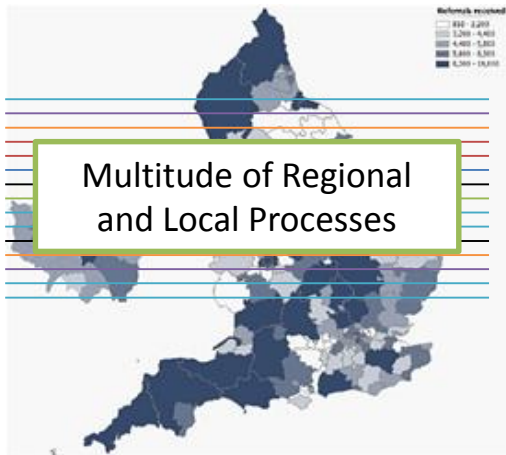


# Widespread adoption very rarely automatic

## Adoption and Access



- Patient access often decided at the regional or local level
- Requires significant payer/clinician engagement



# Summary

- Reimbursement across Europe is complex
- No Silver Bullet
- Important to use networks, advice and support
- Need for tools and programmes that can **support SMEs in signposting, navigation, networking and knowledge sharing**



# THANK YOU!

[eithealth.eu](http://eithealth.eu)

# Supporting small businesses with market access



The eMAPs Project

Erwin Heeneman



Go Global MedTech Accelerator

Joerg Trinkwalter



CRAASH: Moebio Bootcamp

Raquel Riera