

# **Patient Access Model for Medical Devices in Europe**

Reflecting the reality of localised healthcare delivery

22<sup>nd</sup> September 2016



# Supporting the European Commission's focus on health & care



Improving quality and value of care



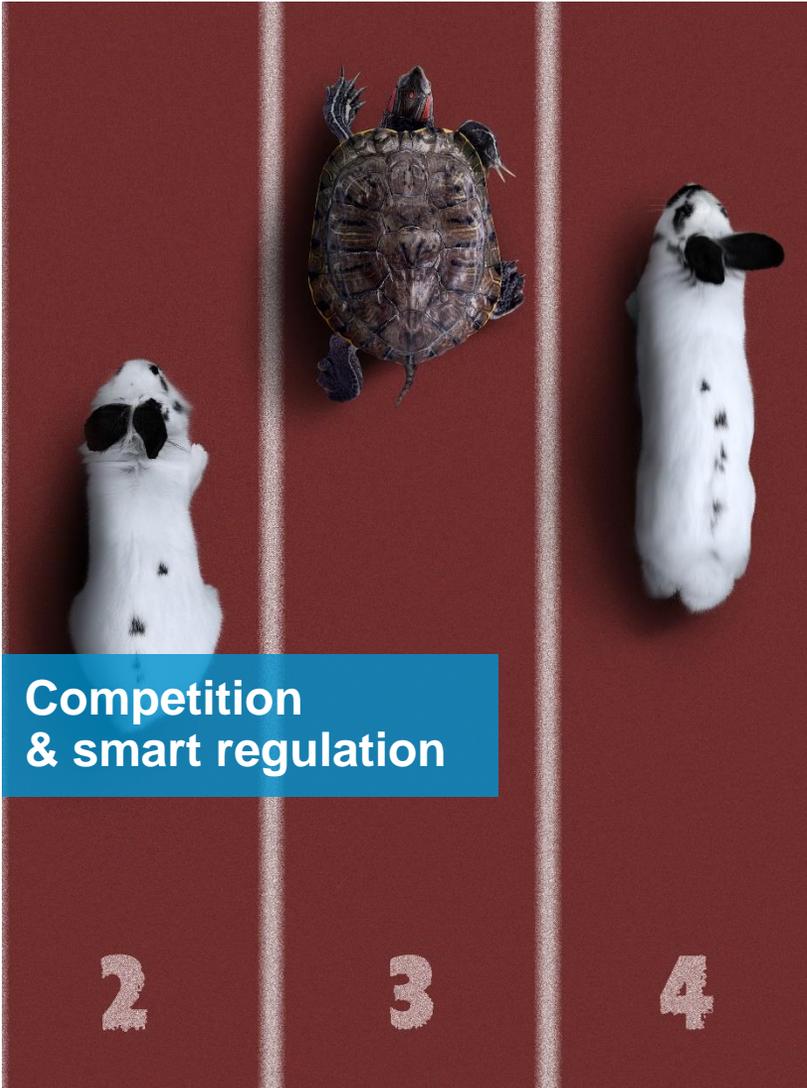
Sustainability of healthcare systems



Effective, timely accessible innovation



# Achieving the European Commission's objectives



Competition  
& smart regulation



EU public procurement  
MEAT

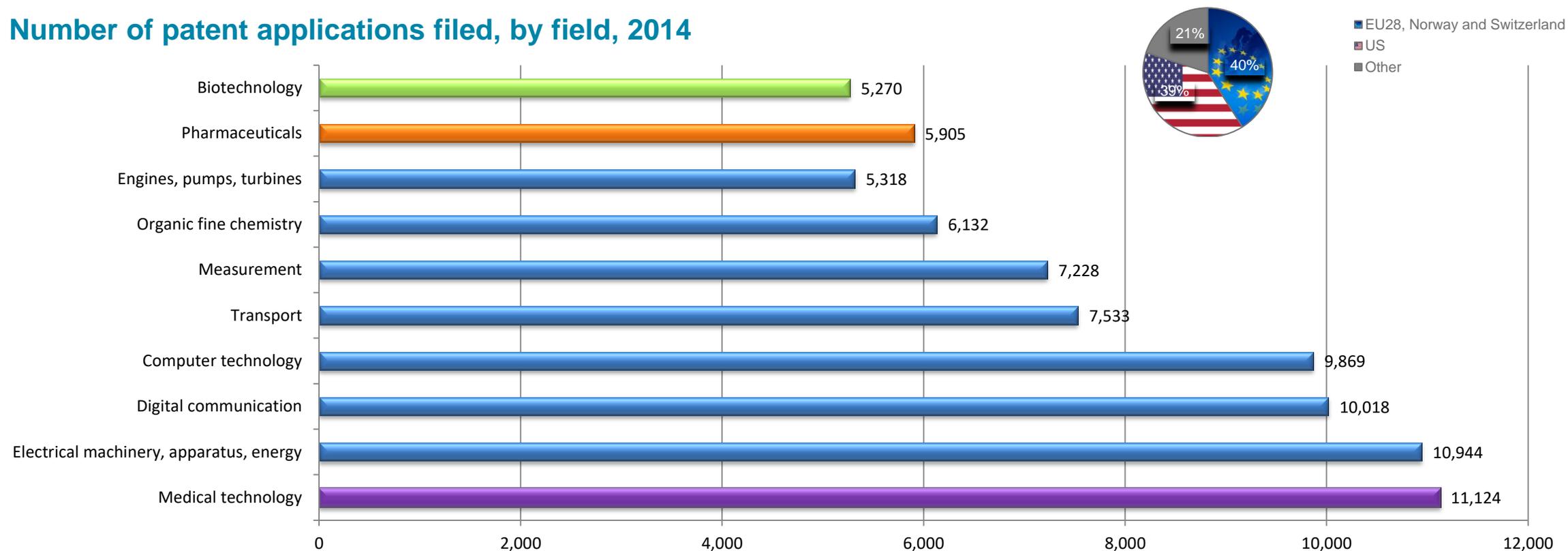


Embrace innovation &  
economic growth



# Context Innovation - Till recent, Europe preferred market to innovate

### Number of patent applications filed, by field, 2014



Analysis based on European patent applications filed with the EPO in 2014 (Direct European applications filed in 2013 and International (PCT) applications entering the European phase in 2014), including divisional applications filed during the year.

Based on the WIPO IPC-Technology concordance as revised in March 2015.

Source: European Patent Office



# Context Sustainability – Value MedTech to Steer HC onto a sustainable path - a competition driven model



2006



2016





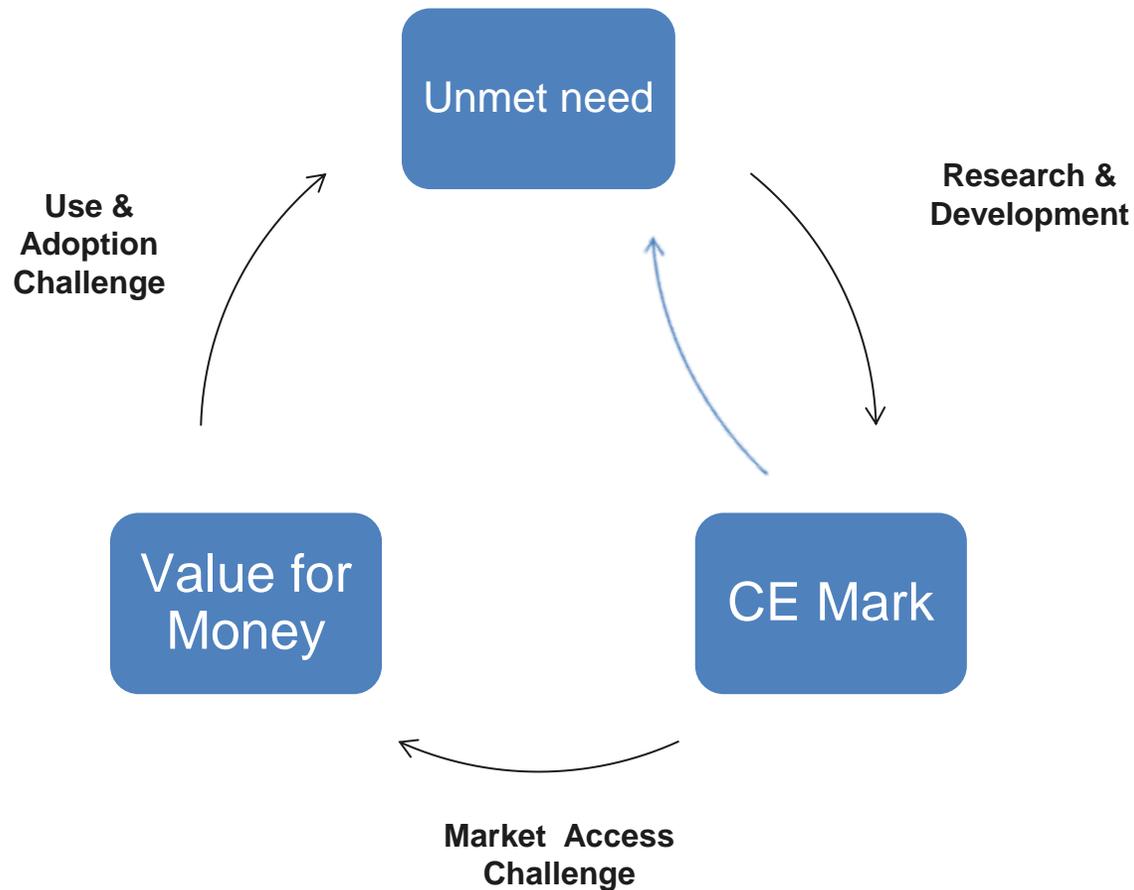
## Access for medical devices

*Decentralised and local decision making*

*Decisions happen at national, regional, local level and are linked to national health or institutional priorities, the health system structure and funding streams.*



# Medical devices access model – Continuous Increase in Value



- Medical devices and access
  - Timely access latest technology
  - Continuous enhancements
  - Learning curve – experience
  - Additional manufacturers
  - Progressive uptake
  - Selective use
  - Effectiveness improvement over time
  - Market driven price pressure
- Localized Incentives
  - Innovation funding
  - Special payments
  - Reimbursement
  - Funding
  - Procurement – competition Pricing



# Medical Devices and Effectiveness – Context Specific



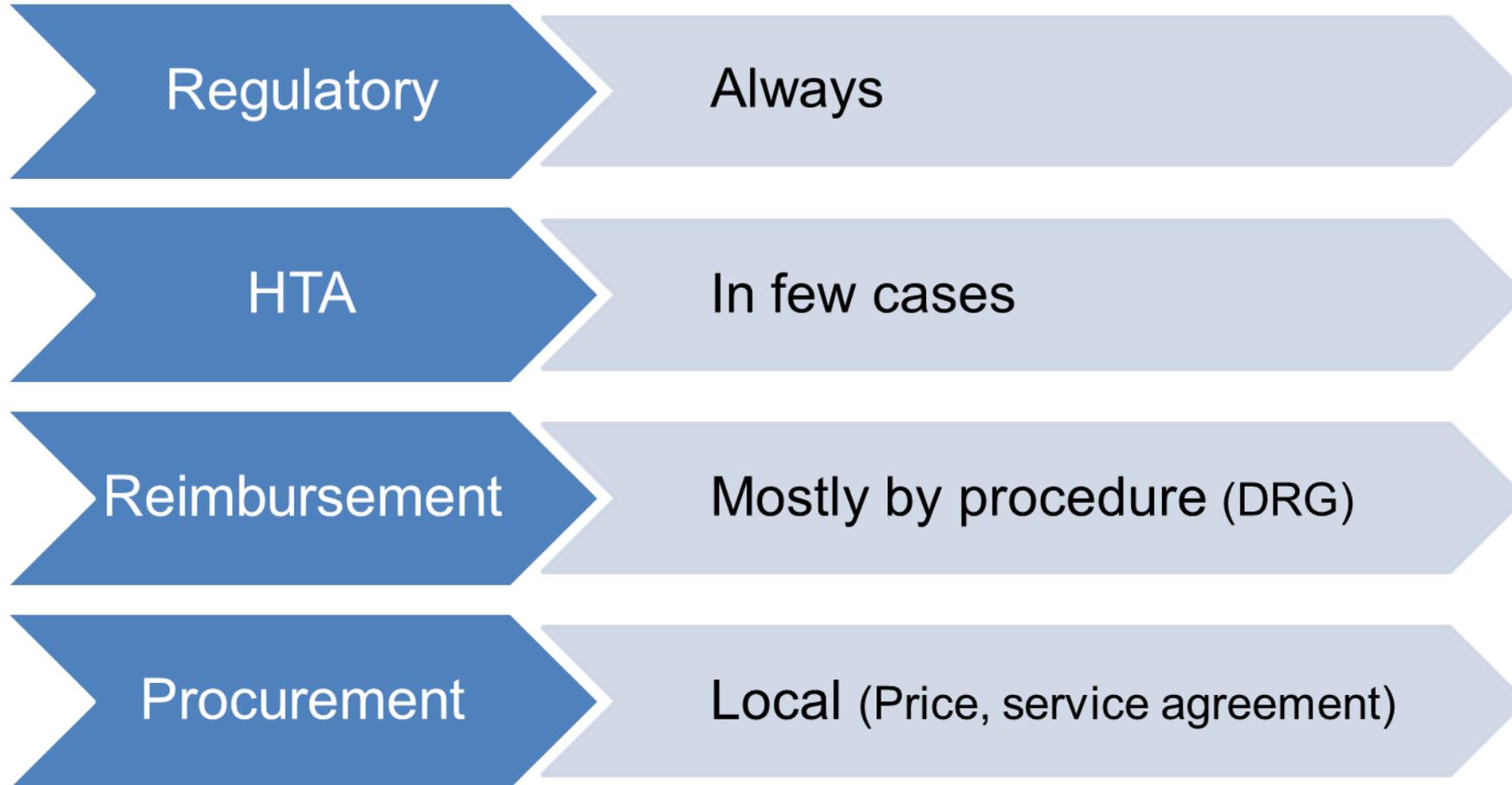


# Medical Devices Access Pathways





## Medical Devices Access model – key considerations



# CE-marking – Pre- and Post-Market Full Lifecycle Monitoring



Safety – Full Lifecycle

Performance



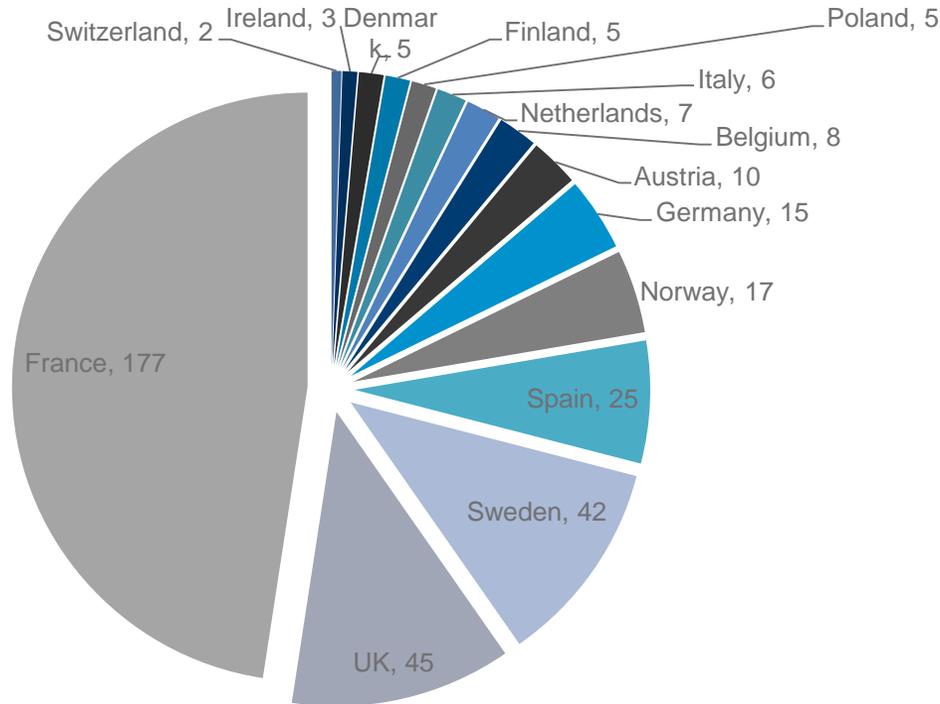
## Use and Value of HTAs – A tool to inform decisions (few cases)



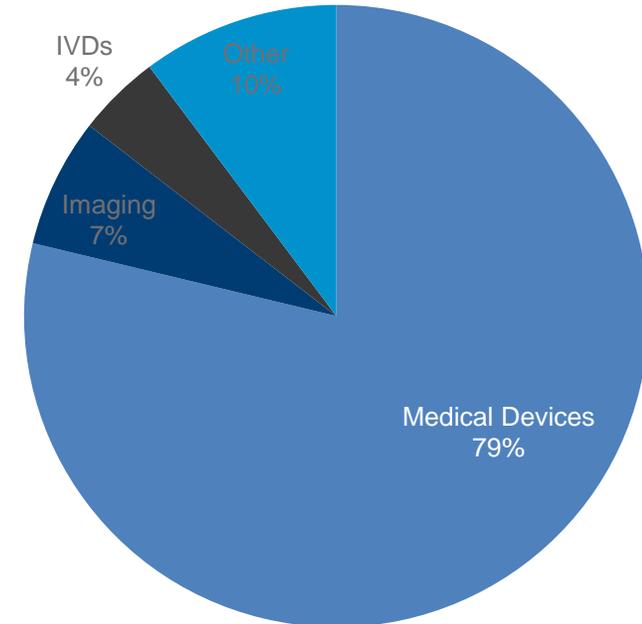


# The use of National/ Regional HTA – few technologies

Total 372 report on 200 Technologies



Number of HTA reports per type of medical technology



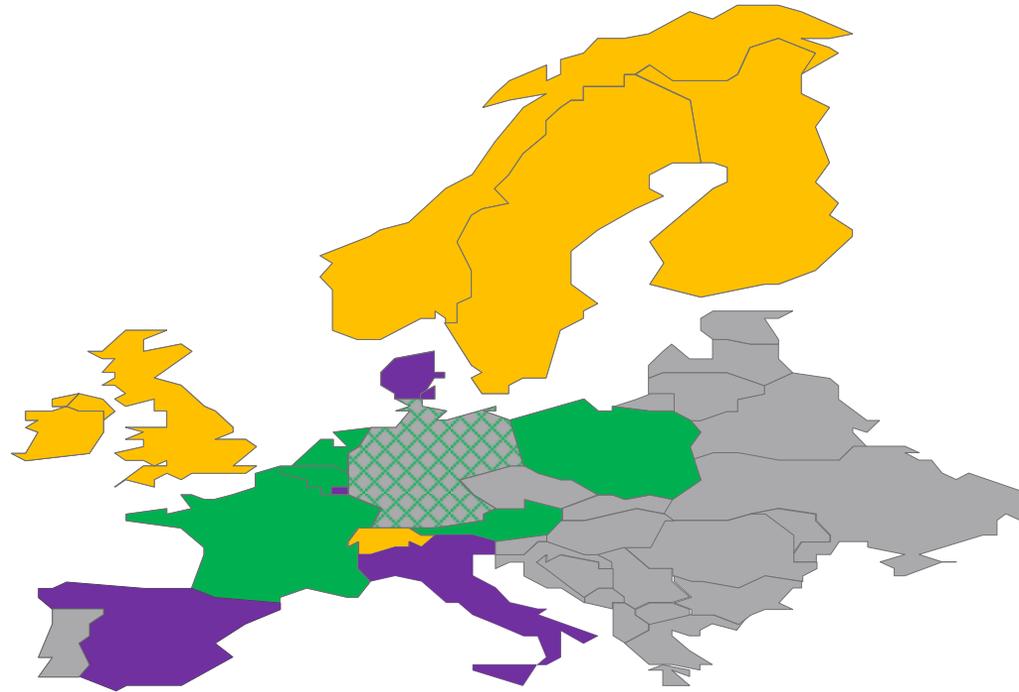
Eucomed analyses based on Synergus HTA database ([link](#))  
EU28 + Switzerland + Norway  
Data represent year 2015  
Hospital / provider HTA excluded

Different HTA agencies use different methodologies, source data and have specific evidence requirements. In few technologies HTA is performed vs yearly 100,000 product subscribed in Repertorio, ~ 10% Class III, 20% Class IIb



# The intended use today of HTA in MD decision making

## Different in Purpose and time



Formal HTA in access pathways and impacts reimbursement and adoption



Formal HTA process with no link to reimbursement but impact on adoption



Very diverse regional HTA; with Variable impact on reimbursement and adoption



Formal HTA with clear link to reimbursement and diffusion in out-patient sector



No, Very sporadic, newly installed HTA





# Number of Medical Devices\* Investigated

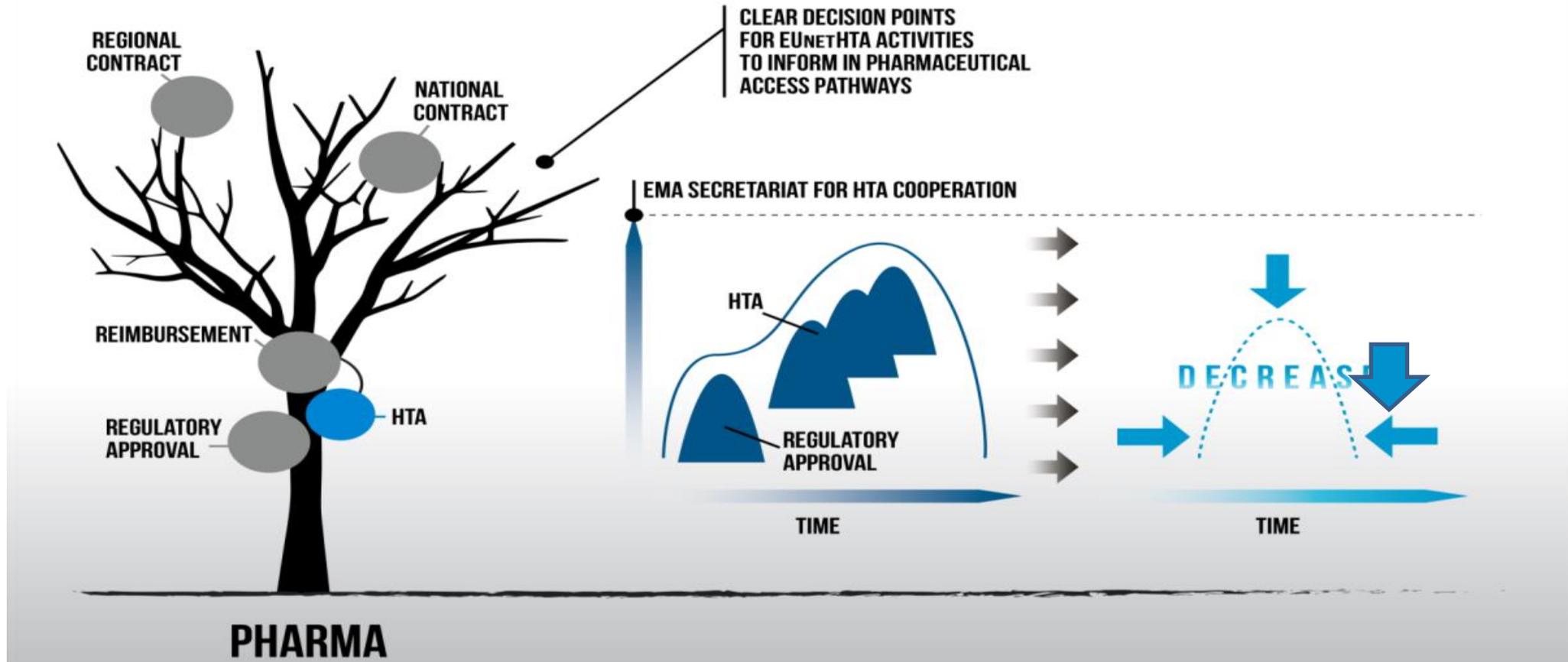
	2014	2015
Total HTA reports on medical devices	289	293
Number of Medical Devices investigated (approximate number)	150	190
<b>Number of Medical Devices looked at by 3 and more countries</b>		
<b>2014</b>		
- Knee replacement: France, UK, Ireland, Spain		
- Hip replacement: France, Ireland, UK		
- Percutaneous aortic valve replacement (TAVI): France, Spain, the Netherlands		
- Bariatric surgery, Sleeve gastrectomy: Norway, Sweden Netherlands		
<b>2015</b>		
- Hip replacement: France, UK, Spain		
- Pacemaker: France, UK, Switzerland		
- Prosthetic intervertebral disc replacement in lumbar spine: France, Belgium, Spain		
<b>Number of Medical Devices looked at by 3 and more countries (excluding France)</b>		
<b>2014</b>		
- Bariatric surgery, Sleeve gastrectomy: Norway, Sweden Netherlands		
- Knee replacement: UK, Ireland, Spain		

\*excluding IVDs, Imaging and other  
Statistic based on Synergus database ([link](#))  
EU28 + Switzerland + Norway

*Current Limited Value of EU joint/collaborative assessment in same year*



# The Use and Value of HTA and EU HTA in Pharma Access Model Inform Pricing & Reimbursement at market entry



# The Direction of Travel of EU HTA

## What is done (JA2)

	Pilot REA* Reports	N.	Time from CE mark
1	Duodenal-jejunal bypass sleeve (obesity)	1	3 yrs
2	Renal denervation systems (TRH)	6	~ 1 yr
3	Biodegradable stents oesophageal stenosis	1	7 yrs
4	Balloon Eustachian tuboplasty	2	0 - 3 yrs
5	Devices for mitral valve regurgitation	3	3 - 7 yrs
6	Mechanical thrombectomy (Stroke)	3	3 - 5 yrs

## What is aimed for (JA3)

- Early dialogues on evidence requirements for HTA
- 43 joint/collaborative REA\*s of non-drug technologies
- Post Launch Evidence Generation
- Quality Standards for Registries

**Unclear :**

**Value proposition and proof of concept ?**

\*REA: Relative Effectiveness Assessments

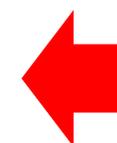


### Conclusion

The available evidence did not allow any final statement to be reached on the relative effectiveness and safety of transcatheter implantable devices for mitral valve repair in adults with moderate-to-severe and severe chronic MR. As recognised by most of the authors, comparative analyses with longer durations of follow-up are believed necessary to clarify the benefits–harms ratio of the 3 procedures.

Two of the devices assessed, NeoChord DS1000 and CARILLON<sup>®</sup> Mitral Contour System<sup>®</sup>, can be considered still at an early stage of development and show small levels of diffusion. Different is the MitraClip<sup>®</sup> case that is not at early stages, counting around 23,000 patients implanted worldwide before results from studies comparing the MitraClip therapy to its claimed comparator (i.e. optimal medical therapy) have been published.

Ongoing studies on CARILLON<sup>®</sup> Mitral Contour System<sup>®</sup> and MitraClip<sup>®</sup> will, in the near future, help to determine whether they are more effective and/or safe than the comparators. For NeoChord DS1000, thorough research, including controlled trials, needs to be conducted to determine whether this device is more effective and/or safe than the comparators, and to verify how long the effects of the treatment remain.





# Reimbursement & Funding - (Access Innovation & (EU) HTA)

Netherlands: DRG as Jan 2014

UK: Commissioning through Evaluation until 2017

Belgium: Reimbursement as of March 1st 2016 until Dec 2020 (w/ conditions)

Switzerland: DRG for the procedure as of Jan 2014\*

France: Reimbursement expected Q4 2016

Spain: Included in National portfolio (w/ registry)



Germany: DRG since Jan 2013

Poland: Reimbursement in 6 centers

Czech Republic: 2 Private insurances agreement

Austria: Temporary code in place. DRG will be requested when RCT data available

Italy: Regional or innovation funding ongoing  
Device reimbursed on top of DRG in Lombardy (80%)

Turkey: SGK coverage in public hospitals\*

Israel: Reimbursement as of Jan 2014

In place    Partial/restricted    Expected

\*conditions apply



# Patient access models for medical technologies and intended use of HTA



*Recognise the differences in health system set-up, funding mechanism, decentralized, localized decision making. Uniqueness of MD access model and need for fit for purpose*

*EU initiatives to be evidence driven, support EU and Member State objectives whilst respecting proportionality and feasibility. MedTech to be a partner !*

# A Value based market access model !

Identify jointly Technologies, Services and Solutions of expected high value for public health, patient and EU citizens well-being, health system sustainability and/or society and

Support streamlined initial access innovation, value demonstration and predictable adoption and use in Europe.

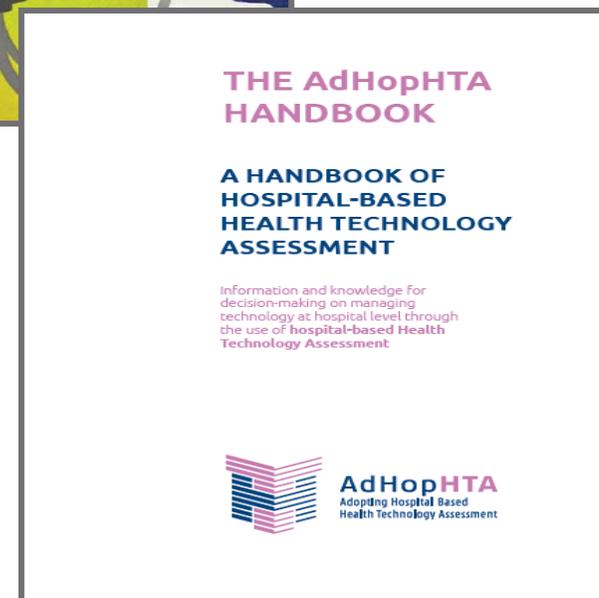
(eg. Disruptive technologies)

Redefine procurement – MEAT Value Based Procurement

BCG/EUCOMED project underway –

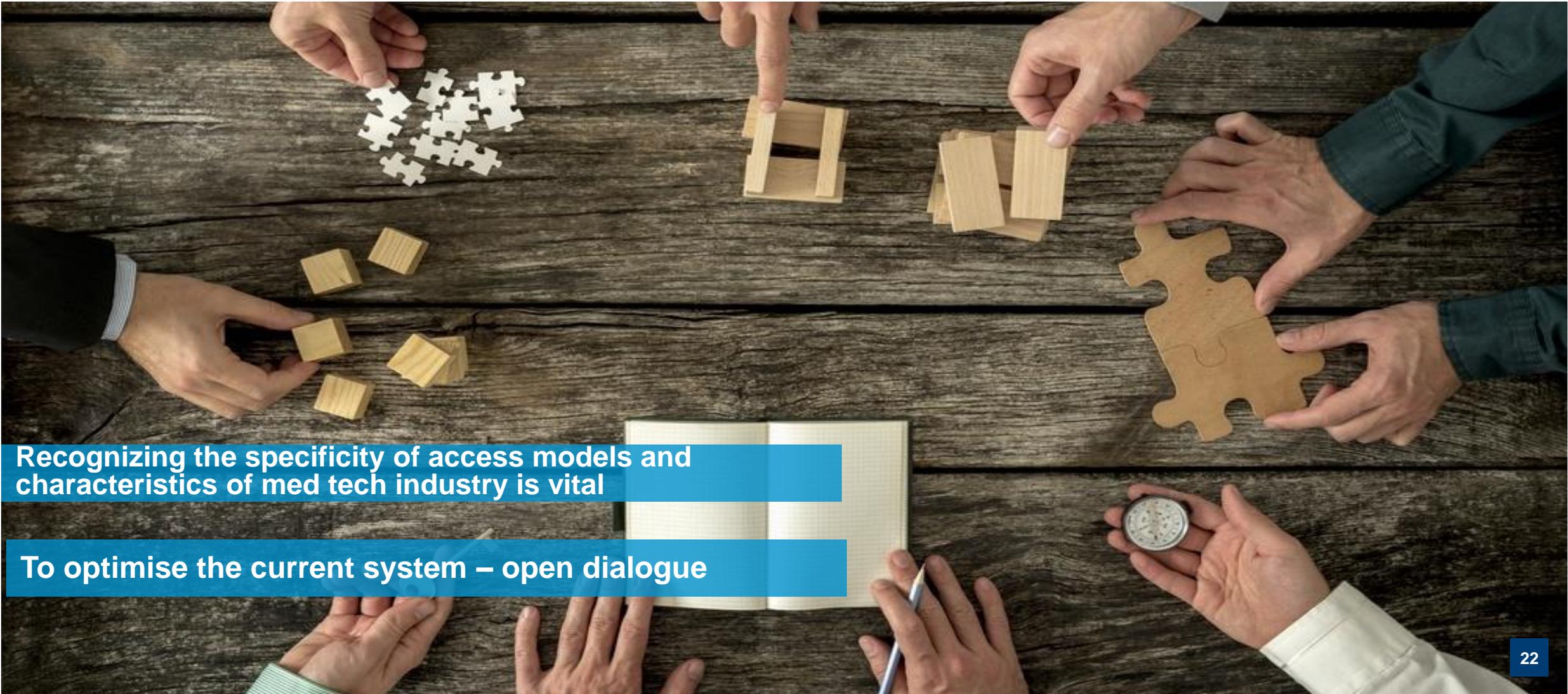
Procurement, the unexpected driver of Value Based Health Care

Evaluation of the value by local (eg. by hospital based HTA) assessments of new technologies, services, solutions





# Conclusion



Recognizing the specificity of access models and characteristics of med tech industry is vital

To optimise the current system – open dialogue