Patient Access Model for Medical Devices in Europe
Reflecting the reality of localised healthcare delivery

22nd 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**

- Biotechnology: 5,270
- Pharmaceuticals: 5,905
- Engines, pumps, turbines: 5,318
- Organic fine chemistry: 6,132
- Measurement: 7,228
- Transport: 7,533
- Computer technology: 9,869
- Digital communication: 10,018
- Electrical machinery, apparatus, energy: 10,944
- Medical technology: 11,124

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

[www.medtecheurope.org](http://www.medtecheurope.org)
Context Sustainability – Value MedTech to Steer HC onto a sustainable path - a competition driven model
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 model – key considerations

- **Regulatory**: Always
- **HTA**: In few cases
- **Reimbursement**: Mostly by procedure (DRG)
- **Procurement**: Local (Price, service agreement)
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

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

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2015</th>
</tr>
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<tbody>
<tr>
<td>Total HTA reports on medical devices</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of Medical Devices investigated (approximate number)</td>
<td>150</td>
<td>190</td>
</tr>
<tr>
<td>Number of Medical Devices looked at by 3 and more countries</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Knee replacement: France, UK, Ireland, Spain</td>
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<td></td>
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<tr>
<td>- Hip replacement: France, Ireland, UK</td>
<td></td>
<td></td>
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<tr>
<td>- Percutaneous aortic valve replacement (TAVI): France, Spain, the Netherlands</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>- Bariatric surgery, Sleeve gastrectomy: Norway, Sweden Netherlands</td>
<td></td>
<td></td>
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<tr>
<td>2015</td>
<td></td>
<td></td>
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<tr>
<td>- Hip replacement: France, UK, Spain</td>
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<td></td>
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<tr>
<td>- Pacemaker: France, UK, Switzerland</td>
<td></td>
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<tr>
<td>- Prosthetic intervertebral disc replacement in lumbar spine: France, Belgium, Spain</td>
<td></td>
<td></td>
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<tr>
<td>Number of Medical Devices looked at by 3 and more countries (excluding France)</td>
<td></td>
<td></td>
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<tr>
<td>2014</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>- Bariatric surgery, Sleeve gastrectomy: Norway, Sweden Netherlands</td>
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</tbody>
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*excluding IVDs, Imaging and other
Statistic based on Synergus database ([link](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)

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

#### 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® Mitral Contour System®, can be considered still at an early stage of development and show small levels of diffusion. Different is the MitraClip® 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® Mitral Contour System® and MitraClip® 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)

- In place
- Partial/restricted
- Expected

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*

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*conditions apply

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

To optimise the current system – open dialogue.