Background

- There is growing interest, activity, and funding to increase the level of HTA collaboration in Europe, with the aim to reduce duplication, increase efficiency, and improve evidence-based decision making.
- The European Commission expectation is that learnings from pilot activity will transform the process into a scalable, sustainable process by 2020.

Methods

- EUnetHTA partners have undertaken 12 pilots evaluating their ability to collaborate on Relative Effectiveness Assessments (REAs):
  - 6 pharmaceuticals, 6 medical devices.
- Johnson & Johnson (J&J) has participated in 5 of the pilots:
  - 2 pharmaceuticals, 3 medical devices.
- A qualitative review of each pilot was conducted to identify opportunities and challenges for introducing collaborative REA.

Johnson & Johnson Pilot Experience

- J&J contributed to 5 pilot REAs:

<table>
<thead>
<tr>
<th>PHARMACEUTICALS</th>
<th>MEDICAL DEVICES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pilot P2:</strong> Canagliflozin (CANA) for Type II diabetes</td>
<td>Pilot MD2: Renal Denervation (hypertension)</td>
</tr>
<tr>
<td><strong>Pilot P6:</strong> Hepatitis C class review of new technologies</td>
<td>Pilot MD4: Balloon Eustachian Tuboplasty (tube disfunction)</td>
</tr>
<tr>
<td><strong>Pilot MD6:</strong> Mechanical Thrombectomy (acute ischaemic stroke)</td>
<td></td>
</tr>
</tbody>
</table>

- The assessments included reviews alongside regulatory approval (P2 & MD4) and after a period post launch (P6 & MD2&6).
- NB: The review of Hep C medicines is still in progress, and class rather than product specific, so is not considered further here.

EUnetHTA REA Timelines

Observations - Pharmaceutical REAs

- The J&J pilot of Canagliflozin was the only REA of a new medicine to run ‘in parallel’ with the EMA regulatory review process, and so the only pilot to provide real insights on the feasibility of such an approach.

Timing of Pilot Initiation wrt CHMP Positive Opinion and EMA Approval

<table>
<thead>
<tr>
<th>PILOT PROJECT</th>
<th>TIME FROM CE MARK m</th>
<th>Length of REA m</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Duodenal-jejunal bypass sleeve (obesity)</td>
<td>7 yrs</td>
<td>7</td>
</tr>
<tr>
<td>2 Renal denervation systems (hypertension)</td>
<td>~1 yr</td>
<td>10</td>
</tr>
<tr>
<td>3 Biodegradable stents (refractory oesophageal stenosis)</td>
<td>7 yrs</td>
<td>14</td>
</tr>
<tr>
<td>4 Balloon Eustachian Tuboplasty (eustachian tube dysfunction)</td>
<td>0-3 yrs</td>
<td>9</td>
</tr>
<tr>
<td>5 Implantable devices (mitral valve regurgitation)</td>
<td>3-7 yrs</td>
<td>11</td>
</tr>
<tr>
<td>6 Mechanical Thrombectomy (acute ischaemic stroke)</td>
<td>3-5 yrs</td>
<td>9</td>
</tr>
</tbody>
</table>

- The studies were ‘unexpected’ for the Company, and required the reallocation of resource from other projects.
- None of the pilots reduced local access requirements. No member state replaced any of their routine process. Some markets referenced the EUnetHTA reports as an extra resource.

Observations - Medical Device REAs

- The pilots were ‘unexpected’ for the Company, and required the reallocation of resource from other projects.
- There appears no predictability to when a technology will be reviewed.
- There appears no clear question (reimbursement, pricing, access), that the pilots were ‘unexpected’ for the Company, and required the reallocation of resource from other projects.
- None of the pilots reduced local access requirements. No member state replaced any of their routine process. Some markets referenced the EUnetHTA reports as an extra resource.

Conclusions

- The pilots demonstrate EUnetHTA Partners can collaborate on REA reports.
- Process and methodological changes are required to deliver a sustainable platform, including earlier & improved stakeholder engagement.
- The pilots have yet to impact on time to patient access or reimbursement.
- For Pharmaceuticals, the issue is HOW best to collaborate? Efficiency gains will depend on process and policy changes within Countries.
- For Medical Devices, the issue is WHY collaborate? At present there is no consistency on what is reviewed, when, or how.
- EUnetHTA must deliver efficiency gains for companies if it is to retain support from Company Boards for future participation in REAs.

EUnetHTA Pilots in Numbers

- 17 – Partners who authored one or more REA reports.
- 4 – The most number of reports a single Author contributed to.
- 5 – Pilots J&J contributed to.
- 1 – Pilot initiated by J&J.