Initiative on Strengthening of the EU cooperation on Health Technology Assessment

DG SANTE B4. Medical products: quality, safety, innovation
Overview

- Why – *The context*

- Where we are - *State of play*

- What - *The initiative*
Initiative for EU cooperation on HTA

Why?

- ensure sustainability of healthcare
- ensure patient access to innovation
- support innovation in Europe

HTA can help
Economic context

Total EU health care expenditure

- **€1 300 billion** per year, including
  - €220 billion for pharmaceuticals and
  - €100 billion for medical devices

- **10% of GDP**

_The figures are forecasted to increase._
What has been done at EU level?

Public Health

- **Projects**
  - 1999-2001: ECHTA/ECHAI
  - 2006-2008: EUnetHTA

- **Joint Actions**
  - 2010-2012: EUnetHTA Joint Action 1
    Scientific/technical cooperation on methodologies and tools.
  - 2012-2015: EUnetHTA Joint Action 2
    Further development of cooperation and piloting of joint assessments.
  - 2016-2020: EUnetHTA Joint Action 3
    Enhanced cooperation with a focus on joint HTA work (e.g. joint assessments and uptake)

Research

- AdhopHTA
- MedtecHTA
- INTEGRATE-HTA
- ADVANCE-HTA

- ADAPT SMART
- GET REAL
EU cooperation on HTA – Where we are

**HTA Network**
- Policy and strategic cooperation
- Art 15 Directive 2011/24
- Set up October 2013
- Permanent

**EUnetHTA Joint Action**
- Scientific and technical cooperation
- Started in the 1990's – EunetHTA 1 & 2
- Joint Action 3 – **Until 2020**
Current shortcomings

- Low uptake of joint work / duplications
- Differences in the procedural framework, capacities and methodological framework of Member States
- No EU-funding mechanism foreseen beyond 2020
Why Now?

- Need for a sustainable mechanisms (post 2020) to build on the success of the current cooperation (EUnetHTA JA3) whilst addressing identified shortcoming

- Calls from Council and EP to propose a "way forward" EU cooperation on HTA
Policy Objectives of the HTA initiative

GENERAL OBJECTIVES:
1. Enable Member States to strengthen their cooperation on HTA in a sustainable manner
2. Ensure a better functioning of the internal market of health technologies;
3. Contribute to a high level of human health protection, as stated in Article 168 TFEU and Article 35 of the Charter of Fundamental Rights.

SPECIFIC OBJECTIVES:
1. Reduce duplication of efforts for HTA bodies and industry;
2. Promote convergence in HTA procedures and methodologies;
3. Improve the uptake of joint work in Member States; and
4. Ensure the long-term sustainability of EU HTA cooperation.
### Policy options

<table>
<thead>
<tr>
<th>Option 1</th>
<th>Option 2</th>
<th>Option 3</th>
<th>Option 4</th>
<th>Option 5</th>
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<tr>
<td>Status quo – voluntary cooperation until 2020</td>
<td>Long-term voluntary cooperation (beyond 2020)</td>
<td>Cooperation through the collection, sharing and use of common tools and data</td>
<td>Cooperation on production of joint REA reports</td>
<td>Cooperation on production of joint Full HTA reports</td>
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Specificities of medical devices sector

- highly heterogeneous technologies
- market access path differs from that of the pharmaceuticals (e.g. frequently through procurement)
- life cycle can be short – quick innovation
- methodological challenges in assessing clinical benefit (e.g. performance depending on operator)
One size does not fit all!

- EC recognises the specificities of Medical Technologies
- Initiative subject to an impact assessment process – **only final when it is final**!

**However**

- To the greatest extent possible, efforts will be made to identify synergies and efficiency/effectiveness gains in relation to the different options
- EU HTA cooperation including medical technologies is already a reality – the question is, what is the way forward ...
Next steps

- Public consultation open until 13 January 2016
- Surveys – launched for facts findings (circulated via Medtech Europe ad COCIR) – January 22
- Impact Assessment process – planned for 2017
- Close cooperation with MS, EP and all key stakeholders

Thank You

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Scientific and Technical cooperation – Medical Devices JA 2 and SEED

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<td><strong>6 joint assessments on medical devices:</strong></td>
<td>• EU project to pilot early dialogues between health technology assessors and healthcare products developers during the development phase of medicinal products &amp; medical devices</td>
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<td>• Balloon Eustachian tuboplasty for the treatment of Eustachian tube dysfunction</td>
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<td>• Biodegradable stents for the treatment of refractory or recurrent benign Oesophageal Stenosis</td>
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<td>• Duodenal-jejunal bypass sleeve for the treatment of Obesity with or without type ii Diabetes Mellitus</td>
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<td>• Endovascular therapy using mechanical thrombectomy devices for acute ischaemic stroke │</td>
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<td>• Renal denervation systems for treatment-resistant hypertension</td>
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<td>• Transcatheter implantable Devices for mitral valve repair in adults with Chronic Mitral Valve Regurgitation</td>
<td>• 3 early dialogues on medical devices</td>
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