Advances in HTA bodies cooperation on Early Dialogues

François Meyer
HAS
Countries involved in WP5

- 38 organisations
- 22 countries

HAS (Lead Partner)
G-BA (Co-lead Partner)
ZIN (A, B1)
HVB (A)
KCE (A)
IPH-BE (B1)
RIZIV-INAMI (A)
NCPHA (A)
CIPH/HZJZ (A, B1, B2)
MoH Cyprus (A)
UTA (B1)
FIMEA (B1)
IQWiG (A)
EKAPTY SA (B1, B2)
NIPN (A)
AIFPA (A, Strand B1 AC lead; B2) SNHTA (A, B1)
AGE.NA.S (A)
DGFDM IT (B1)
Veneto/CRUF (A, B1)
RER (A, B1)
UCSC GEMELLI (B1)
Hdir (A, B1)

AOTMt (A)
INFARMED (A, B1)
NSPHMPDB (A)
UniBA FOF (B1)
JAZMP (A, B1)
NIJZ (B2)
AQUAS (A, B1)
AEMPS (A)
AVALIA-T (A, Strand B1 AC lead)
OSTEBA (B1)
AETS SA (A, B1)
AETS ISCIII (A)
MPA (A)
TLV (A, Strand B1 AC lead)
NICE (A, Strand B2 AC lead)

WP5 A: 28 partners, 16 experienced in Early Dialogues
Involvement of HTA bodies (HTAB) in Early Dialogues (ED) / Scientific Advice (SA)

• **SA by one single HTAB**
  - Started in 2009
  - NICE, G-BA, AIFA, HAS...
  - HTAB only or in parallel with national regulatory agency

• **SA by multiple HTABs:**
  - Started in 2012: EUnetHTA:
    13 Early Dialogues
  - Dedicated project:
    **SEED Shaping European Early Dialogues:**
    14 HTABs coordinated by HAS.
    11 EDs, 4 in parallel with EMA
  - Enhanced participation and coordination at the HTA level
Early Dialogues  Cooperative actions at HTA bodies level

2006

- EUnetHTA Project
  2006-2008
  Inception

2016

- Joint Action 1
  2010-2012
  Putting into practice

- Joint Action 2
  2012-2015
  Strengthening practical application

- Joint Action 3
  2016-2020
  Turning pilots into standard practice

- EUnetHTA EDs
- SEED
  2013-2015
  Parallel with EMA
Early Dialogues  Cooperative actions at HTA bodies level

- EUnetHTA Collaboration

2006
- EUnetHTA Project 2006-2008
  - Inception

2016
- Joint Action 1 2010-2012
  - Putting into practice
- Joint Action 2 2012-2015
  - Strengthening practical application
- Joint Action 3 2016-2020
  - Turning pilots into standard practice

- EUnetHTA EDs
- SEED 2013-2015
  - Parallel with EMA

- EMA: Parallel Scientific Advice

European network for Health Technology Assessment | JA3 2016-2020 | www.eunethta.eu
## Highlights from Year 1

### WP5A – Early Dialogues

<table>
<thead>
<tr>
<th>Choice of HTA bodies (HTAB) involved</th>
<th>EMA-HTA Parallel Scientific Advice</th>
<th>EMA-SEED/EUnetHTA Parallel Early Dialogues</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preference expressed by company</td>
<td>Decided by SEED partners</td>
<td></td>
</tr>
<tr>
<td>Company seeks HTA availability</td>
<td>SEED Coordinator</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Recruitment of participating HTABs</th>
<th></th>
<th></th>
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<tbody>
<tr>
<td>Company seeks HTA availability</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Coordination role among HTABs</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>HTA coordinator</td>
<td>Yes</td>
<td>One HTA list of issues</td>
</tr>
<tr>
<td>One HTA list of issues</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exchanges between HTABs</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Exchange of pre-meeting HTA</td>
<td>Exchange of pre-meeting HTA</td>
<td></td>
</tr>
<tr>
<td>positions</td>
<td>positions more intensive</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Final outcome</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual written HTA answers</td>
<td>Compilation of HTA answers</td>
<td></td>
</tr>
<tr>
<td>with an effort to reach consensus</td>
<td>with an effort to reach consensus</td>
<td></td>
</tr>
<tr>
<td>when possible</td>
<td>when possible</td>
<td></td>
</tr>
</tbody>
</table>
Experience so far

*Improvements since 2013 (in EMA PSA and SEED)

- Involvement of patients
- Coordination of HTA bodies in SEED (prep and follow-up)
- Experience of EMA PSA sessions co-chaired by SAWP and HTA bodies
- Questions and feedback prior to the face-to-face meeting is much more a consolidated effort

*Further improvements needed (based on EMA PSA and EUnetHTA/SEED)

- Simplify logistics: single point of contact/project management
- More consistent & predictable HTA engagement, with dedicated resources and capacity building across HTAs
- Appropriate time to allocate to discussion of issues, with open discussions
- Clear, aligned and written output from HTA advice, similar to CHMP SA letter
Improvement of SA/ED by HTA bodies (1)

Improve quality and consistency:

- Set up of a stable group of experienced HTA bodies with significant experience in the conduct of EDs: consistency, quality, learning

Improve the output from HTA bodies

- Appointment of coordinator and rapporteur for EDs => to increase the proportion and quality of common answers

▶ Set up of a Working Party (initially called Standing Committee)
Early Dialogue Working Party (EDWP)

Gathers HTA bodies with important experience in EDs AND important commitment to participate in EUnetHTA EDs

EDWP members are HTA bodies experienced in collaborative EDs:
- With availability of adequate expertise
- With commitment to participate
- With appropriate budget

Questions:
- How many members?
- What members to chose?
- How many EDs per year?
Early Dialogue Working Party (Cont.)

Decisions:

- Call for expression of interests among WP5a partners
- Check of the participation criteria
- Flexibility: possibility of a shared seat, or a member + alternate
- “Big” countries represented, but also Eastern Europe and mid-size countries

Budget:

- Hybrid financing of EDs introduced: EDs Financed by EUnetHTA budget or fees
- Limit: around 15 EDs budgeted for the first two years. Not possible to engage the EDWP for more.

Participation of HTABs not members of EDWP

- Small number of additional HTABs possible for each ED.
Improvement of SA/ED by HTA bodies (2)

Consider extension in product lifecycle:
  • to cover Post Launch Evidence Generation (PLEG)

Improve logistics and project management:
  • EUnetHTA ED secretariat

Maintain flexibility:
  • Multi HTA and parallel advice with EMA both available
Improvement of coordination: current status

Strong coordination at scientific and organizational levels

- Rotating scientific coordination:
  
  HAS will lead for the first 5 SA/EDs with G-BA acting as rapporteur;

  These roles will switch for the next 5 SA/EDs;

- Permanent organizational coordination (EUnetHTA ED Secretariat)

  HAS throughout all JA3
Parallel SA/ED with EMA

Development of a solution

*Initial plan:*
- to run in parallel
  - the EMA driven Parallel Scientific Advice
  - the EUnetHTA driven Parallel Early Dialogues
- To merge the two processes (by end of JA3?)

*Adaptation*
- Difficulties and risks to run two separate platforms for parallel advice…
- New EUnetHTA proposal after interaction with EMA:
  - To **centrally recruit** HTA bodies for all parallel ED/SA
  - To **ensure coordination** between HTA bodies during the whole process
  - To engage the **EDWP** for some of the parallel EDs/SAs, according to selection criteria
Thank you

Any questions?
One process for parallel regulator-HTA

Early Dialogues/Scientific advice:
EUnetHTA actors and process

Session 1: EUnetHTA JA3 progress

EUnetHTA Forum

presented by Hannah Bruehl
Scientific Officer, Federal Joint Committee
What is new / different?

- **Enhanced collaboration between EMA and EUnetHTA**
- **Single gateway** for requests for parallel discussions before start of pivotal clinical trials on initial evidence generation for MAA/Reimbursement and Post Licensing Evidence Generation.
- **Central recruitment** of HTABs via EUnetHTA ED Secretariat
What is new / different?

• **EUnetHTA ED Secretariat** = point of contact in relation to all HTA aspects
• **New deadlines** for submission of letter of intent and draft briefing document
• Presubmission TC only in exceptional cases
What is new / different?

- New documents:
  - Guidance
  - Letter of Intent
  - Briefing document
EUnetHTA Actors

**EUnetHTA ED Secretariat**
- Responsible for all practical coordination/project management of HTABs.
- Acts as the sole HTAB contact point.
- Responsible for insuring the acceptability of the Letter of Intent.

**Early Dialogues Working Party (EDWP)**
- Is a standing committee of HTABs to ensure robust high-quality HTA outputs.
- All EDWP members will participate in procedures selected for Consolidated PC unless justified exceptions.

**The Early Dialogue Committee (EDC)**
- Is constituted for a specific product and the members will fluctuate to a degree for each Consultation.
EUnetHTA Actors

EDC Scientific Coordinator
- undertakes scientific coordination on behalf of HTAs.
- facilitates discussion between HTABs in advance of meetings.
- interacts with the EMA.
- acts as a co-chair for the HTABs for the F2F meeting.

HTAB Rapporteur (only PCC)
- Collects and consolidates responses from EDC
- Presents consolidated HTAB answers during the F2F meeting.
- Interacts with the EDC Scientific Coordinator and EMA on scientific matters.
Process - 2 pathways for parallel consultations

Parallel consultation – individual (PCI)
- EMA + voluntary HTABs coordinated by EUnetHTA

Parallel consultation – consolidated (PCC)
- EMA + EUnetHTA EDWP + voluntary HTABs
- EMA / EUnetHTA Parallel Consultation Procedure (+/- EDWP participation according to prioritization)
Process - EUnetHTA EDWP selection criteria

- The product should aim to bring added benefit to patients i.e. by:
  - A new mode of action for the indication
  - AND targeting a life-threatening or chronically debilitating disease
  - AND responding to unmet need (no treatment or only unsatisfactory treatment available)

- →EDs should represent a wide array of topics, therapeutic areas etc.
## Process - PC Pathway Implications

<table>
<thead>
<tr>
<th></th>
<th>Individual</th>
<th>Consolidated</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HTAB recruitment</strong></td>
<td>EUnetHTA ED Secretariat</td>
<td>EUnetHTA ED Secretariat</td>
</tr>
<tr>
<td><strong>Mode of HTAB participation</strong></td>
<td>Voluntary HTAB participation</td>
<td>Full EDWP + up to 3 additional HTABs</td>
</tr>
<tr>
<td><strong>Selection criteria</strong></td>
<td>Do not apply</td>
<td>Apply</td>
</tr>
<tr>
<td><strong>Outcome</strong></td>
<td>Individual HTABs’ written answers, sent via EUnetHTA ED Secretariat</td>
<td>Single written report including consolidated HTAB written answers for shared positions, and individual HTAB answers where no consensus was possible</td>
</tr>
<tr>
<td><strong>Fees</strong></td>
<td>~ PSA: participation of HTABs according to fees paid (- partners)</td>
<td>EUnetHTA budget and fees for some partners</td>
</tr>
</tbody>
</table>
Process - EUnetHTA EDC

The Early Dialogue Committee (EDC) is constituted for a specific product and the members will fluctuate to a degree for each Consultation.

Individual PC

Consolidated PC

The preferences of the Applicant (indicated in the Letter of Intent) will be taken into account, but participation of those HTABs cannot be guaranteed.

Composition of the EDWP as of Sept. 14th 2017: France (HAS), Germany (G-BA), United Kingdom (NICE), Italy (AIFA with alternate RER), Hungary (NIPN), and a shared seat for The Netherlands/ Belgium (ZIN/ RIZIV-INANMI)
Process - steps

**Applicant**
- Day - 60: Applicant sends letter of intent to EMA secretariat
- Day - 30: Applicant sends draft BB to EUnetHTA ED Secretariat
- Day - 2: Applicant sends final BB to EMA secretariat
- Day + 45: Applicant sends response to list of issues to EMA/EUnetHTA

**EMA/EUnetHTA**
- Prioritization by EDWP according to selection criteria
- Day - 15: Clarification request on draft BB
- Day + 30: List of Issues

25 Evidence generation EUnetHTA Forum
Process - steps

**Applicant**

- **Day + 56**
  - Applicant sends **power point presentation**
  - to EMA secretariat

- **Day + 60**
  - Face to face meeting with the Applicant, EMA and EUnetHTA EDC (max 3 h)

- **Day + 67**
  - Applicants sends **minutes**
  - to EMA secretariat

**EMA/EUnetHTA**

- **Day + 56**
  - EUnetHTA ED Secretariat &
  - EMA secretariat

- **Day + 60**
  - Optional discussion of late changes

- **Day +70/+75**
  - Final advice letter/final written recommendations

Evidence generation EUnetHTA Forum

14 Sept 2017
One process for parallel regulator-HTA Early dialogues/Scientific advice

Session 1: EUnetHTA JA3 progress

EUnetHTA Forum

Presented by Jane Moseley on 14 September 2017
Senior Scientific Officer – Scientific Advice Office
Disclaimer

The views presented are those of the individual and may not be understood or quoted as being made on behalf of the European Medicines Agency (EMA) or reflecting the position of EMA or one of its committees or working parties or EUnetHTA.

No conflicts of interest
Outline

Parts 1 and 2 EUnetHTA speakers: background and process Parallel Consultations
Part 3 for Parallel Consultation – General and EMA issues

- Procedural experience
- Regulatory actors
- General principles
- Patients engagement
- Summary of key messages
Experience with parallel regulatory/HTA advice

Parallel EMA HTA procedures

Since Launch of New platform
Transitioned/registered - 8
  • PCI 4
  • PCC 2
  • Pending 2

* To Sept 2017
Regulators

Committee for Medicinal Products for Human Use (CHMP)

Scientific Advice Working Party SAWP

SAWP Coordinators

Scientific Advice Secretariat

Other stakeholders (beyond HTABs)

Clinical experts

Patient representatives

Healthcare professionals

Others (as appropriate) (e.g. payers)
Patient engagement recognised and integral part of the Agency’s work

For Parallel Consultations - Individual patient experts identified

- through patient organisations under the EMA framework for interaction - EMA - patients – consumers (EMA/637573/2014)
- Capacity-building / training / briefing
- A pool of patients acting as experts in their disease and its management
- Invited to attend all teleconferences and the EMA HTA Applicant meeting;
- Also declare conflicts of interest, managing barriers to participation

Item on EMA-EUnetHTA workplan

Task force on patient involvement established at EUnetHTA level (cross workpackage)
Principles

Roles and remits

- Multi-stakeholder procedure - equal partners - adherence

Confidentiality and Conflict of interest (COI)

- EMA code of conduct and EMA policy on access to documents, and COI (policy 43, Policy 44)
- An EUnetHTA Declaration of Interest Confidentiality Undertaking Conflict of Interest; Letter of intent; Briefing documents and presentations

Status of Parallel Consultation outputs - not legally binding

- EMA justify any deviations from the advice given
- HTABs reflects state-of-the-art medical science & national requirements
Publically available information

EMA In new platform for parallel consultation as per current SA procedures, Annex to CHMP


EMA as per current SA procedures: nothing before completion of decision making process (MA) in line with access to documents policy

Published - Monthly

**Pre-authorisation: scientific advice and protocol assistance EMA centralised procedures**

<table>
<thead>
<tr>
<th></th>
<th>1995 - 2016</th>
<th>2017</th>
<th>Overall total</th>
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</thead>
<tbody>
<tr>
<td>Scientific Advice</td>
<td>3215</td>
<td>178</td>
<td>3393</td>
</tr>
<tr>
<td>Follow-up to Scientific Advice</td>
<td>938</td>
<td>62</td>
<td>1000</td>
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<tr>
<td>Protocol Assistance</td>
<td>735</td>
<td>51</td>
<td>786</td>
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<tr>
<td>Follow-up to Protocol Assistance</td>
<td>355</td>
<td>27</td>
<td>382</td>
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<tr>
<td>HTA parallel advice</td>
<td>87</td>
<td>14</td>
<td>101</td>
</tr>
<tr>
<td>Qualification of novel methodologies</td>
<td>94</td>
<td>11</td>
<td>105</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>5424</strong></td>
<td><strong>343</strong></td>
<td><strong>5767</strong></td>
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</table>

June 2017
## Published – Monthly Adoptions at CHMP

<table>
<thead>
<tr>
<th>Substance</th>
<th>Intended indication(s)</th>
<th>Type of request</th>
<th>Topic</th>
<th>Significant Benefit</th>
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<tbody>
<tr>
<td>HTA parallel advice</td>
<td>Treatment of castrate-resistant prostate cancer.</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>SA</td>
<td>PA</td>
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<tr>
<td>HTA parallel advice</td>
<td>Treatment of Crohn’s disease.</td>
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<td>SA</td>
<td>PA</td>
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<tr>
<td>HTA parallel advice</td>
<td>Treatment of ulcerative colitis.</td>
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<td>SA</td>
<td>PA</td>
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<tr>
<td>HTA parallel advice</td>
<td>Treatment of psoriasis.</td>
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<td>SA</td>
<td>PA</td>
</tr>
<tr>
<td>HTA parallel advice</td>
<td>Treatment of insomnia.</td>
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<td>SA</td>
<td>PA</td>
</tr>
</tbody>
</table>

* = Requested

June 2017
Key Messages

New significant positive development on collaboration for parallel advice/early dialogue between EMA and EUnetHTA

- New platform, one gateway for all procedures
- Centralised HTA recruitment,
- HTA working party for prioritised subset with consolidated HTA advice
- For all parallel advice/early dialogue procedures - Streamlined logistics, greater HTA coordination
- Platform for parallel discussion on initial evidence generation for MAA/reimbursement, and post licensing evidence generation
Key messages 2

- Multi-stakeholder, EMA and EUnetHTA equal partners, working together, benefits patient access and public health
- Respect for roles and remits to facilitate optimised evidence generation for different stakeholders
- Building on successes of PSA and SEED and Interactive focused meetings
- Launched 03 July 2017
- 8 products transitioned to or registered under new scheme
Thank you for your attention

Further information

Contact EMA scientificadvice scientificadvice@ema.europa.eu

Contact EUnetHTA ED secretariat eunethta-has@has-sante.fr

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Send a question via our website www.ema.europa.eu/contact

Follow us on @EMA_News
Update on the progress of jointly produced assessments in WP4

EUnetHTA Forum, 14th of September 2017
Amsterdam

Lead Partner: Norwegian Institute of Public Health, Norway
Co-Lead Partners: National Health Care Institute, The Netherlands, Ludwig Boltzmann Institute for Health Technology Assessment, Austria
EUnetHTA Partners in WP4

Large number (~60) of regional agencies and non-for-profit organisations that produce or contribute to HTA
WP4 – Joint Production

- **Lead Partner**: Norwegian Institute of Public Health – NIPHNO

- **Co-Lead Partner Other technologies** – Ludwig Boltzmann Institute for Health Technology Assessment, Austria

- **Co-Lead Partner Pharmaceuticals** – Zorginstituut Nederland
Objectives WP4 General

- **Production** of Joint and Collaborative Assessments

- **Refine the production processes** of jointly produced assessments based on lessons learned and experiences from JA2 and current Joint Assessments

- **Facilitate the implementation** of Joint Assessments in national/local practice
<table>
<thead>
<tr>
<th>Joint Assessments</th>
<th>Collaborative Assessments</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Centralised Project management by WP4 Co-Leads</td>
<td>• Decentralised Project management by WP4 Co-Leads and Activity Centre Departments</td>
</tr>
<tr>
<td>• EUnetHTA processes and quality management</td>
<td>• EUnetHTA processes and quality management</td>
</tr>
<tr>
<td>• Topic selection and prioritisation process (ongoing)</td>
<td>• Topic selection based on national work program (min. 3 partners interested in collaboration)</td>
</tr>
<tr>
<td>• Use of submission file</td>
<td>• Optional use of submission file</td>
</tr>
<tr>
<td>• Use of HTA Core Model and EUnetHTA guidelines</td>
<td>• Use of HTA Core Model and EUnetHTA guidelines</td>
</tr>
<tr>
<td>• Broad and standardised stakeholder involvement (mandatory scoping meetings with industry)</td>
<td>• Optional scoping meetings with industry</td>
</tr>
</tbody>
</table>
Tools & templates

Guidelines provide methodological guidance

Assessment template and Project Plan template provide guidance for reporting

Guidelines on Methodological Issues:

Comparators and comparisons
- Criteria for choice of most appropriate comparator(s)
- Methods of comparison: direct and indirect comparisons

Outcomes
- Clinical endpoints
- Surrogate endpoints
- Composite endpoints
- Health-related quality of life
- Safety

Level of evidence
- Internal validity
- Applicability

+ checklist for ethical, organisational, social and legal issues

Procedure manual describes processes – to be replaced by SOPs

Submission File template is submitted by manufacturer (optional for Collaborative Assessments) – to be updated in JA3
WP4 ACA: Pharmaceuticals

ZIN (WP4 Co-LP), The Netherlands
Objectives

Year 1
Production of **2 Joint Assessments** that are fit for purpose, of high quality, of timely availability

Year 2
Production of **6 Joint Assessments** that are fit for purpose, of high quality, of timely availability
### 3 ongoing Joint Assessments

#### 2 Joint Assessments started in year 1

<table>
<thead>
<tr>
<th>Assessment Code</th>
<th>Treatment</th>
<th>Indication</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTJA01</td>
<td>Midostaurin</td>
<td>Acute Myeloid Leukaemia</td>
<td>Novartis</td>
</tr>
<tr>
<td>PTJA02</td>
<td>Regorafenib (Stivarga©)</td>
<td>Monotherapy for the treatment of adult patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib</td>
<td>Bayer</td>
</tr>
</tbody>
</table>

#### 1 Joint Assessment started in year 2

<table>
<thead>
<tr>
<th>Assessment Code</th>
<th>Treatment</th>
<th>Indication</th>
<th>Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>PTJA03</td>
<td>Alecensa</td>
<td>Monotherapy for the first-line treatment of adult patients with ALK+ advanced NSCLC</td>
<td>Roche</td>
</tr>
</tbody>
</table>
EU Regulatory Process

- EMA Process
- CHMP opinion

WP4 HTA Process

- Expression of interest from pMAH
- Preparation of draft submission file from pMAH
- Development draft project plan
- Scoping meeting with pMAH
- Finalization of project plan
- Receive final submission file
- Co-production of 1st version of REA
- 2nd version of REA (Including editorial review)
- Consultation
- Final version of REA

Stakeholder involvement

- Identification of clinical experts and patients
- Review project plan by clinical experts
- Involvement of patients
- MAH provides evidence file
- Review by external experts and fact check by MAH

Local REA’s (e.g. national, regional)
Goals for Year 2

➢ Increase production of Joint Assessments
➢ Refine production process to facilitate national uptake
  ➢ Produce SOPs together with WP6
➢ Refine tools/templates
  ➢ E.g. submission file template
WP4 ACB: Other Technologies

LBI-HTA (WP4 Co-LP), Austria
Objectives

Year 1: production of 2 Joint Assessments and 3 Collaborative Assessments that are fit for purpose, of high quality, of timely availability

Year 2: production of 2 Joint Assessments and 6 Collaborative Assessments that are fit for purpose, of high quality, of timely availability

➢ Probe the decentralised project management of jointly produced assessments by Activity Centre Departments
6 Activity Centre Departments

- Face-to-face **training meeting** May 2017
- Training material
- **Support** by LBI HTA
- Project management of **Collaborative Assessments**
3 published Collaborative Assessments

OTCA01: Wearable cardioverter-defibrillator (WCD) therapy in primary and secondary prevention of sudden cardiac arrest in patients at risk – Nov 2016

OTCA02: Antibacterial-coated sutures versus non-antibacterial-coated sutures for the prevention of abdominal, superficial and deep, surgical site infection (SSI) – April 2017

OTCA05: Repetitive transcranial magnetic stimulation for treatment-resistant major depressive disorder – April 2017
4 ongoing Collaborative Assessments

OTCA03: Screening of fetal aneuploidies whereby non-invasive prenatal test (NIPT) – *due in January 2018*

OTCA04: Added value of using gene-expression signature for adjuvant chemotherapy decisions in early breast cancer (MammaPrint) – *due in January 2018*

OTCA06: Transcatheter aortic valve implantation (TAVI) in patients at intermediate surgical risk – *due end 2017*

OTCA07: Relative effectiveness assessment of Femtosecond laser-assisted cataract surgery (FLACS) compared to standard ultrasound phacoemulsification cataract surgery – *due in May 2018*

No published or ongoing Joint Assessments.
Production Process: Stakeholder involvement

**Topic selection and Team building**
- Contacting patient organisations, medical societies; contacting industry

**Development of Project Plan**
- Review of project plan by external experts, optional involvement of patients (e.g., focus group, review of project plan), fact check by manufacturers
- JA: scoping meeting with manufacturers
- Manufacturers provide evidence

**Completion of Submission File (optional in CA)**

**Production of 1st draft assessment:**
- Internal review by EUnetHTA partners

**Production of 2nd draft assessment:**
- External review

**Production of final assessment:**
- Medical editing and layout

**National/local uptake**
## National Uptake of Assessments

<table>
<thead>
<tr>
<th>JA or CA</th>
<th>Organisation and country</th>
<th>Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st CA: Wearable cardioverter-defibrillator (WCD)</td>
<td>Galician Agency for Health Technology Assessment (AVALIA-t), Spain</td>
<td>Will use EUnetHTA HTA Adaptation toolkit to adapt CA and use the report to support reimbursement decisions in the health system.</td>
</tr>
<tr>
<td></td>
<td>Agency for Quality and Accreditation in Health Care and Social Welfare (AAZ), Croatia</td>
<td>CA will be summarized in Croatian and kept to support possible decision making (will then add supplementary country specific information).</td>
</tr>
<tr>
<td></td>
<td>State Health Care Accreditation Agency (VASPVT), Lithuania</td>
<td>Adaptation; used CA (full report) and added information relevant for the Lithuanian context.</td>
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<tr>
<td>2nd CA: Antibacterial-coated sutures (SSI)</td>
<td>National Institute of Pharmacy and Nutrition (OGYEI), Hungary</td>
<td>If they receive submission; CA will be used in critical assessment which support decision making activities (reimbursement decisions)</td>
</tr>
<tr>
<td></td>
<td>VASPVT, Lithuania</td>
<td>Adaptation; used CA (full report) and added information relevant for the Lithuanian context.</td>
</tr>
<tr>
<td></td>
<td>AAZ, Croatia</td>
<td>Used CA (full report) a package (with Croatian summary and recommendations) to develop a new clinical guideline on hospital infections in Croatia.</td>
</tr>
<tr>
<td>5th CA: Repetitive transcranial magnetic stimulation</td>
<td>Belgian Healthcare Knowledge Centre (KCE), Belgium</td>
<td>Will use CA for ‘KCE has Read for you’: a short summary and assessment of a publication from another organisation complemented with information and data relevant for the Belgian context.</td>
</tr>
<tr>
<td></td>
<td>AAZ, Croatia</td>
<td>CA will be summarized in Croatian and kept to support possible decision making (will then add supplementary country specific information).</td>
</tr>
</tbody>
</table>
Goals for Year 2

➢ produce Joint Assessments: development of topic selection processes
➢ raise the number of Collaborative Assessments/ year
➢ train the Activity Centre Departments in managing assessments independently
➢ update processes and produce SOPs together with WP6
Thank you

Any questions?