EUnetHTA
Joint HTA production

Marcus C. Guardian, Chief Operations Officer, EUnetHTA
EUnetHTA JA3 Participants

81 partners of 29 countries, consisting of national, regional and non-for-profit agencies that produce or contribute to HTA

Project Coordinator:
The Dutch National Health Care Institute (ZIN)
Joint Action 3 Objectives

Sustainable model for joint HTA work

Increase use, quality and efficiency of HTA

- Increase collaboration
- Increase production
- Increase usage
- Sharing knowledge
- Alignment of processes
- Implementation
EUnetHTA Stakeholders

- Patients & Consumers
- Health Care Providers
- Technology Producers
- EUnetHTA stakeholders
- Research & Academia
- Regulators
- Payers & Decision Makers
### EUnetHTA HTA Core Model®

#### SCOPE

- **Clinical domains**
  - Comprehensive/ Full HTA
- **Non-clinical domains**

#### HTA Core Model DOMAINS

1. Health problem and current use of technology
2. Description and technical characteristics
3. Safety
4. Clinical effectiveness
5. Costs and economic evaluation
6. Ethical analysis
7. Organisational aspects
8. Patient and social aspects
9. Legal aspects
Joint HTA production

- Early Dialogue (ED)/Scientific Advise
- Joint Clinical Assessments (JCA)
- Horizon Scanning
- Post Launch Evidence Generation (PLEG)

Non-Duplication

Benchmarking against highest possible quality standards

Standardisation of procedures, templates, SOPs, guidelines
Thank you!
Timelines Joint Assessment dependent on CHMP

- EMA process
- CHMP opinion
- EU market authorisation

HTA preparatory
- Receive Letter of Intent
- Resource allocation - selection of assessment team
- Assessment scope (PICO)

HTA assessment
- Assessment phase

HTA publication
- Publication final Joint Clinical Assessment report
- ~4 weeks after EU market authorisation

Production of JCA max. 100 days

National HTA/ decision making
EU Regulatory Process

WP4 HTA Process

Stakeholder involvement

Expression of interest from Health Technology Developer (HTD)

Letter of Intent

Develop PICO

All HTA bodies provide input

Scoping meeting with HTD

Submission file

CHMP opinion

Co-production of 1st version of JCA

By author and co-author

EU Market Authorisation

2nd version of JCA

Incorporating feedback other HTA bodies

Input on scope (PICO)

HTD provides submission file

Input on scope (PICO)

HTD provides submission file

Review by external experts

fact check by HTD

Final version of JCA

Expert input & fact check HTD

National HTA/decision making process

Timeline (days)
Early Dialogues

Company / Applicant

Request to EMA

EMA SA

EMA SA procedure

Simultaneous request to EMA and EUnetHTA

Parallel Consultation

EMA: Eligibility
EUnetHTA: Eligibility & Prioritization

EMMA + voluntary HTABs

low priority for HTA = Individual Parallel Consultation (PCI)

EMA + EDWP members

high priority for HTA = Consolidated Parallel Consultation (PCC)

EUnetHTA multi-HTA ED

EUnetHTA multi-HTA procedure (EDWP participation)

Request to EUnetHTA

EUnetHTA: Eligibility & Prioritization
Early Dialogues

Parallel Consultations

One procedure, 2 pathways

- PCI - products NOT meeting EDWP selection criteria; not eligible for use of EUnetHTA budget (except for coordination tasks)
- PCC - products meeting EDWP selection criteria; EUnetHTA budget can be used (but some agencies may be financed with fees)

Clear priorities for the involvement of EDWP:

Prioritization criteria to target products aimed at bringing added benefit to patients, i.e.:

- New mode of action for the indication AND
- Targeting life-threatening or chronically debilitating disease AND
- Responding to unmet need
Timelines for one Early Dialogue

1. **D -30** Draft Briefing Document
   - Pathway, EDC, EDC Scientific Coordinator, EDC Rapporteur
   - By EUnetHTA ED Secretariat

2. **D 0** Final Briefing Document
   - Compiled Written Request for Clarification D -15
   - By EDC Scientific Coordinator

3. **D +30** e-Meeting EDC
   - Compiled Draft Written Positions and Issues D +25
   - By EUnetHTA ED Sekretariat

4. **D +60** F2f-Meeting
   - Compiled Draft Written Recommendations D +50
   - By EDC Rapporteur, validated by EDC Scientific Coordinator

5. **D ~+70** Final Deliverable
   - Compiled Final Written Recommendations D +67
   - By EUnetHTA ED Secretariat
   - Final deliverable for PCI
   - Final Consolidated HTA ED Written Answers D +475
   - By EDC Scientific Coordinator
   - Final deliverable for PCC/Multi-HTA

6. **D +75** Final Deliverable
   - Final Consolidated HTA ED Written Answers D +70
   - Only in case of PCC or Multi-HTA Early Dialogue

**Input from partners**

**Output**

Stephanie Said, G-BA
Health Providers (HTA Network Stakeholders)

- Council of European Dentists (CED)
- European Association of Hospital Pharmacists (EAHP)
- European Forum for Primary Care (EFPC)
- European Hospital and healthcare Federation (HOPE)
- European Public Health Association (EUPHA)
- European Society of Cardiology (ESC)
- European Society of Medical Oncology (ESMO)
- European Union of General Practitioners/ Family Physicians (UEMO)
- Pharmaceutical Group of the European Union (PGEU)
- Standing Committee of European Doctors (CPME)
Pharmaceutical Joint Assessments

<table>
<thead>
<tr>
<th>Title</th>
<th>Status</th>
<th>Author; Co-author; Reviewer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Midostaurin for AML</td>
<td>Published – Nov. 2017</td>
<td>Finland, Norway, Sweden, Netherlands, France, UK, Spain</td>
</tr>
<tr>
<td>Regorafenib for hepatocellular carcinoma</td>
<td>Published – Oct 2017</td>
<td>France, Portugal, Croatia, Switzerland, Finland, Austria, Hungary, Spain</td>
</tr>
<tr>
<td>Alecensa for ALK+ advanced NSCLC</td>
<td>Published – Jan. 2018</td>
<td>Sweden, Austria, Croatia, UK, Italy, Spain, Hungary</td>
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<tr>
<td>Sotagliflozin for Type 1 diabetes mellitus</td>
<td>Ongoing</td>
<td>Sweden, Netherlands, Spain, Switzerland, Latvia, Portugal, Ireland, Poland</td>
</tr>
<tr>
<td>Enasidenib for AML</td>
<td>Ongoing</td>
<td>Norway, Spain, France, Italy, Switzerland, Scotland, Malta</td>
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**Level of Implementation**

- PTJA01 Midostaurin: 10
- PTJA02 Regorafenib: 11
- PTJA03 Alecensa: 8
## Uptake PTJA01 - Midostaurin

<table>
<thead>
<tr>
<th>Country</th>
<th>Agency</th>
<th>Details of use</th>
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<tbody>
<tr>
<td>Italy</td>
<td>AIFA</td>
<td>Used for background information</td>
</tr>
<tr>
<td>Spain</td>
<td>AEMPS</td>
<td>Cited in the national report as background or additional information</td>
</tr>
<tr>
<td>UK (Scotland)</td>
<td>HIS</td>
<td>Used for validation of submission from the technology developer</td>
</tr>
<tr>
<td>Croatia</td>
<td>AAZ</td>
<td>A summary of the report was prepared in the national language, as well as assessment elements B0001 and A0020, with links to the full report on English language. Upon Croatian decision makers request on this topic, the report will be updated if needed and local information will be added (i.e. epidemiological information such as patient numbers; the technologies available in Croatia; information about costs;..), including recommendations</td>
</tr>
<tr>
<td>Spain</td>
<td>AETSA</td>
<td>A summary of this EUnetHTA assessment in Spanish together with the full English report has been published on AETSA’s website for dissemination. In addition, the report has been distributed to the regional decision-makers and hematologists</td>
</tr>
<tr>
<td>UK</td>
<td>NICE</td>
<td>EUnetHTA reports are indexed in the NHS evidence, a public database which provides access to selected sources of evidence in health, social case and public health</td>
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<tr>
<td>France</td>
<td>HAS</td>
<td>Cited in the national report as background or additional information</td>
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## Uptake PTJA02 - Regorafenib

<table>
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<tr>
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<tr>
<td>Austria</td>
<td>LBI-HTA</td>
<td>National adaptation. Made no changes to the information used, added recommendations</td>
</tr>
<tr>
<td>France</td>
<td>HAS</td>
<td>The national report structure is partly based on the REA, especially for the EFF and SAF parts. Most of the references used in the TEC and CUR parts are also in the national report. Final REA was transmitted to the HTA committee members before the national assessment. Cited in the national report as background or additional information</td>
</tr>
<tr>
<td>Italy</td>
<td>AIFA</td>
<td>Efficacy and safety information used as supportive information in national report. Cited in the national report as background or additional information</td>
</tr>
<tr>
<td>Portugal</td>
<td>INFARMED</td>
<td>National adaptation, translated some sections of the REA for use in national report and added recommendations</td>
</tr>
<tr>
<td>Spain</td>
<td>AEMPS</td>
<td>Cited in the national report as background or additional information</td>
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<tr>
<td>UK (Scotland)</td>
<td>SMC</td>
<td>Used for background information</td>
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<tr>
<td>Croatia</td>
<td>AAZ</td>
<td>A summary of the report was prepared in the national language, as well as assessment elements B0001 and A0020, with links to the full report on English language. Upon Croatian decision makers request on this topic, the report will be updated if needed and local information will be added (i.e., epidemiological information; the technologies available in Croatia, costs), including recommendations</td>
</tr>
<tr>
<td>Spain</td>
<td>AETSA</td>
<td>A summary of this assessment in Spanish together with the full English report has been published on AETSA's website for dissemination. In addition, the report has been distributed to region decision makers and oncologists</td>
</tr>
<tr>
<td>UK</td>
<td>NICE</td>
<td>Used as background information to check that similar issues were being identified in national assessment. In addition, EUnetHTA reports are indexed in NHS Evidence, a public database which provides access to selected sources of evidence in health, social case and public health.</td>
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</tbody>
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