EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA activities related to synergies between regulators and HTA bodies

EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting

15 March 2017

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The wider picture: Reference points for exploring synergies

Strategy paper (link):

HTA NETWORK REFLECTION PAPER ON "SYNERGIES BETWEEN REGULATORY AND HTA ISSUES ON PHARMACEUTICALS"

ADOPTED BY THE HTA NETWORK, 10 NOVEMBER 2016

a) Pre-marketing phase

b) Market Entry

c) Post Marketing - Real world effectiveness and safety

Scientific and technical cooperation:

1/ EUnetHTA Joint Action 3, particularly work packages 4 and 5

Work Package 4 - Joint Production

Work Package 5 - Life cycle approach to improve Evidence Generation

2/ EMA/EUnetHTA bilateral (since 2010)

Work plan 2012-2015 reported, new work plan in development

Areas identified in the Reflection Paper on synergies between regulatory and HTA issues

Pre-marketing	Market entry	Post-marketing
• Process for early dialogue / scientific advice • Unmet medical need definition • Evidence from various sources • Horizon scanning • Stakeholder dialogue • Research needs	• Identification of treatment eligible population • Facilitation of relative effectiveness assessment • Optimisation of reports	• Design of post-marketing studies • Concept of "late dialogues" • Real world data generation

Others: orphan medicines, personalised medicines, vaccines, patient preferences, PRO/QoL tools

Most developed: parallel EMA/HTA scientific advice (early dialogue)

Starting point: Newly licensed medicines do not reach all patients in need

Regulators and HTAs

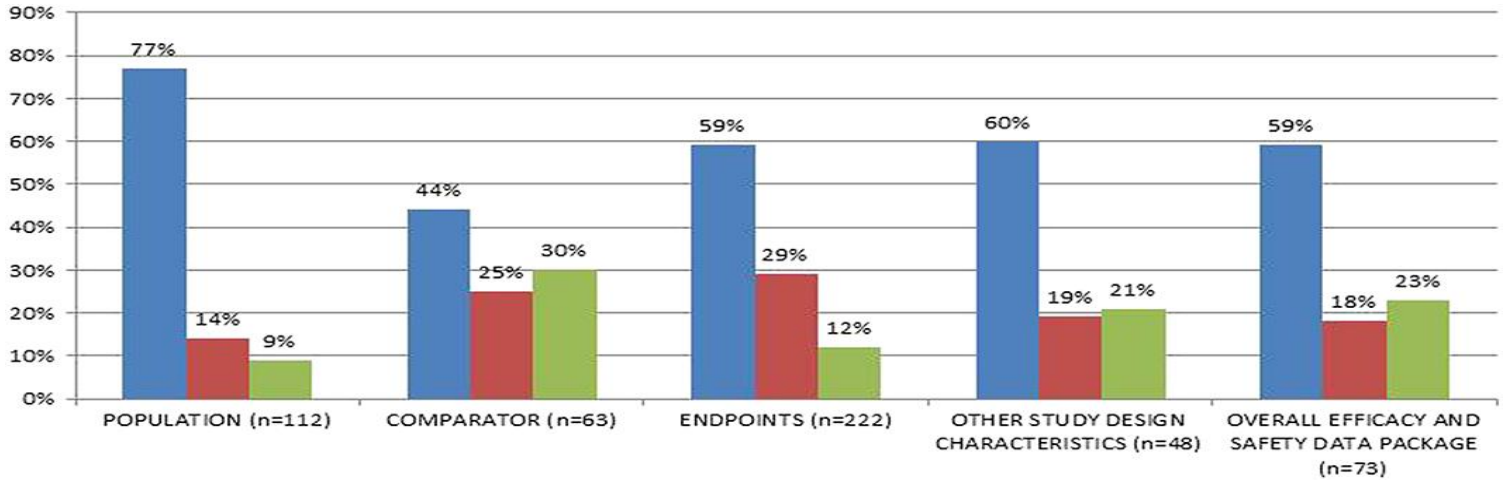
- answer different questions
- have different requirements in terms of evidence

Aim: decision makers come together early

- to discuss the planned development including
- Populations/Comparators/design of trial/endpoints

Expectation: Optimised development plan ➔ Improve access for patients

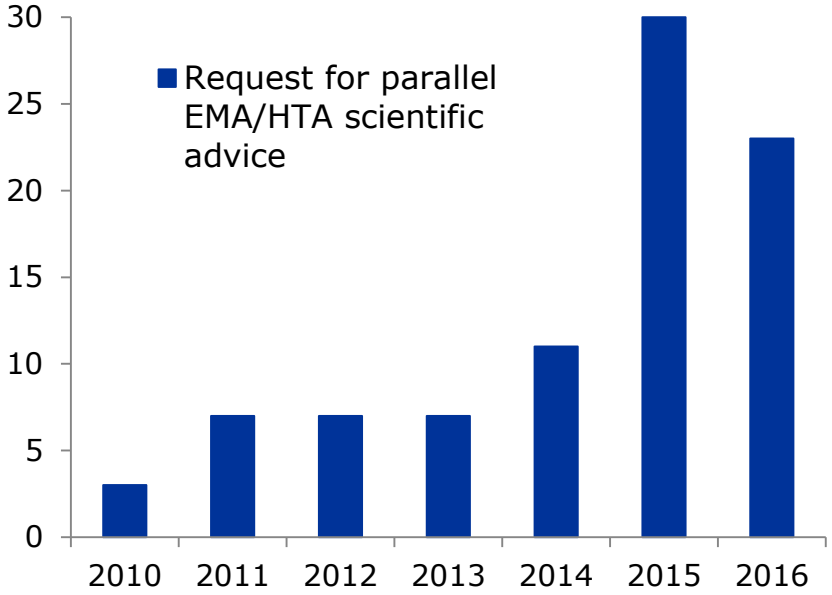
How aligned are the perspectives of EU regulators and HTA bodies?



Level of agreement for each domain: Health Technology Assessment bodies (HTABs) *vs.* regulators (based on 31 procedures). *n* represents the total number of HTABs expressing an opinion for each domain. ■full agreement ■partial agreement ■disagreement.

British J Clin Pharm, Volume 82, Issue 4, pages 965-973, (http://onlinelibrary.wiley.com/doi/10.1111/bcp.13023/full#bcp13023-fig-0003)

Experience with parallel EMA/HTA advice procedures



- In 2016, SMEs accounted for a quarter of the requests received for parallel scientific advice with HTA bodies.
- For all discussion meetings the involvement of patients is facilitated.
- So far in 2017 there have been 21 requests for parallel EMA/HTA scientific advice.

Other examples of areas for ongoing or expected collaboration

PRIME (PRIority-MEdicines) scheme: support to medicines that offer a major therapeutic advantage over existing treatments, or benefit patients with no treatment options

From regulatory opinion to REA: facilitate to reduce time lag between regulatory and reimbursement decisions, and to reduce divergences across HTA bodies

Post-licensing data generation: one (set of) studies for regulators and HTA bodies (payers), including real-world evidence; to enable refined and extended benefit-risk assessment as well as value assessment and pay-for-performance schemes

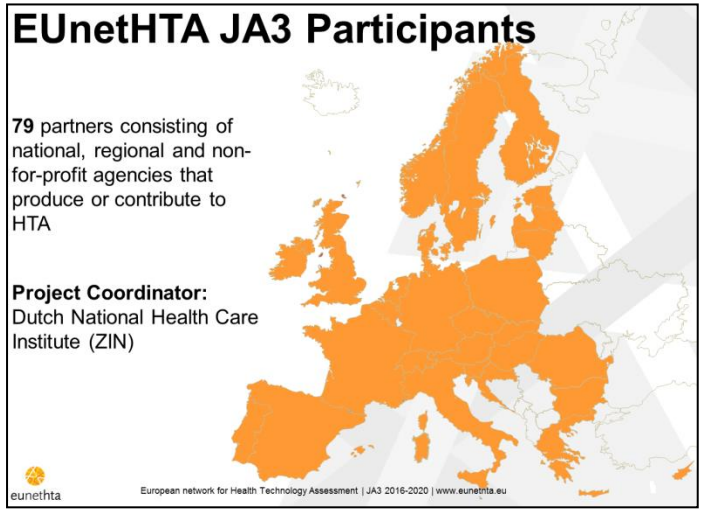
Registries: explore the extent to which patient registries might be suitable for answering HTA–related questions

Overview of EUnetHTA Joint Action 3

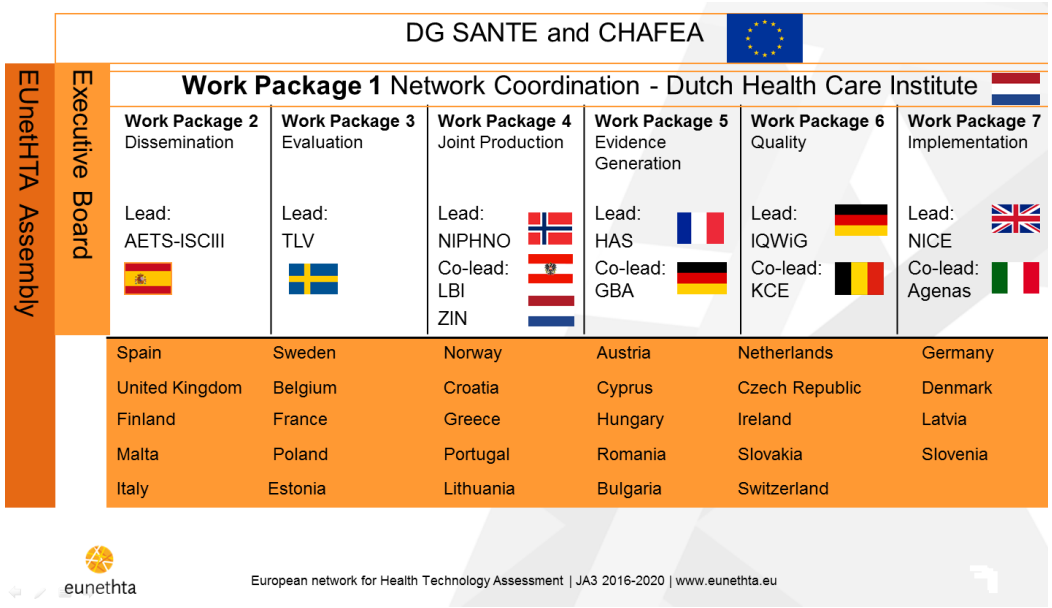
For a sustainable network on Health Technology Assessment (HTA) in Europe

Specific objectives of JA3:

- To increase production of high-quality HTA joint work
- To increase uptake and implementation of joint HTA work at the national, regional, and local level
- To support evidence-based, sustainable, and equitable choices in healthcare and health technologies



EMA contribution to Joint Action 3



- WP 4 – joint production (contribution is here with regard to exchange after CHMP Opinion)

- WP5 – life-cycle approach to improve evidence generation:
  part a = early dialogues
  part b = post-licensing evidence generation

On the horizon: Options for HTA collaboration beyond 2020

1. Inception Impact Assessment for an initiative for strengthening EU cooperation on HTA
2. Public consultation on a future initiative aiming for strengthening the EU cooperation on HTA

Key characteristics	Option 1 The status quo –voluntary cooperation on HTA (until 2020)	Option 2 Long term voluntary cooperation on HTA (beyond 2020)	Option 3 Cooperation on collection, sharing and use of common tools and data	Option 4 Cooperation on the production of joint REA reports	Option 5 Cooperation on the production of joint full HTA reports
Regulatory	Non-legislative	Non-legislative	Legislative	Legislative	Legislative
Participation of HTA bodies and industry	Voluntary	Voluntary	Compulsory (tools) Voluntary (HTA)	Compulsory (tools) Voluntary / compulsory (HTA)	Compulsory (tools) Voluntary / compulsory (HTA)
Uptake joint output	Voluntary	Voluntary	Compulsory for tools	Compulsory for tools and REA	Compulsory
Financing	Largely depending on EU budget Ending 2020	Largely depending on EU budget Long-term	Mixed funding model (EU budget + MS + industry contribution) Long-term	Mixed funding model (EU budget + MS + industry contribution) Long-term	Mixed funding model (EU budget + MS + industry contribution) Long-term
Main joint output					
a. Common Tools/templates	(✓)	(✓)	✓	✓	✓
b. Joint REA	(✓)	(✓)	(✓)	✓	✓
c. Joint Full HTA	(✓)	(✓)	(✓)	(✓)	✓
d. Early Dialogue	(✓)	(✓)	✓	✓	✓

Domains of (untapped) synergies between regulators and HTAs

Collaboration in the PRIME scheme

Linking existing initiatives on horizon scanning

Most developed: early dialogue / parallel scientific advice

Potential collaboration on "Late dialogues"

Exchange on the regulatory assessment / label to ensure better understanding

Patient registries to address different uncertainties (clinical, economic, health system utility)

HTA-regulatory collaborations need to reflect appropriate balance between the enabler and the gatekeeper roles to ensure effective, well-aligned and sustainable healthcare systems in EU.

Thank you for your attention

Further information

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