EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Parallel Consultations

An overview of the procedure

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An agency of the European Union

Outline

Parallel advice with HTAs

- Rationale and Impact of parallel advice
- European level landscape for advice

New procedure

- HTA actors, outline of the process and outcomes
- Experience since launch

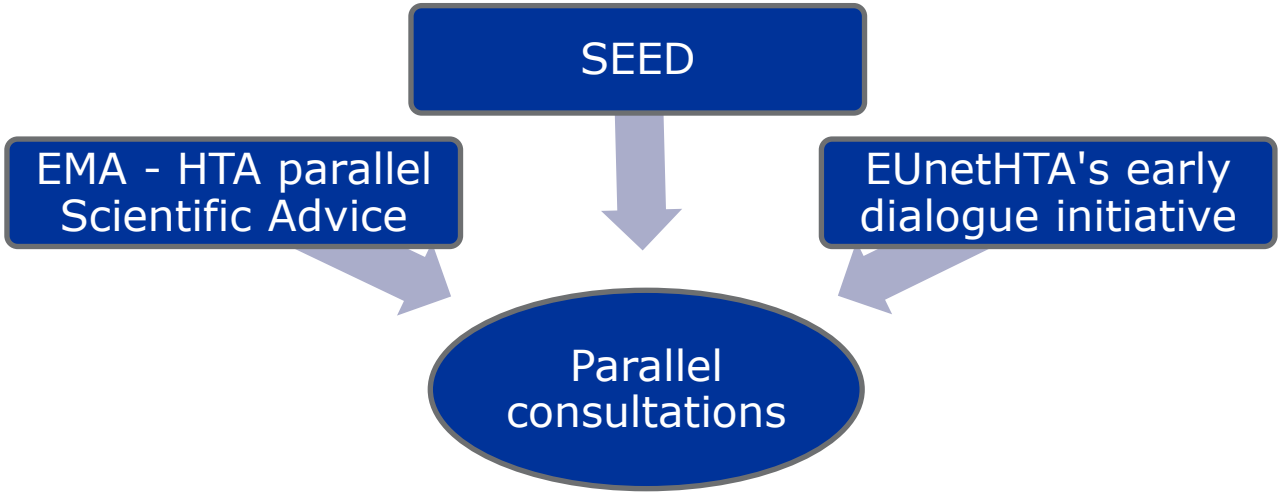
Key messages

Background

- **Starting point:** Regulators and Health Technology Assessment (HTA) bodies come together early
  - to discuss the planned development
- **Expectation:** Optimised development plan ➔ efficient ➔ Improve access for patients
- **How best to do this interaction?**

- Recently launched single platform
- EMA and EUnetHTA as equal partners

Why and how we have got here



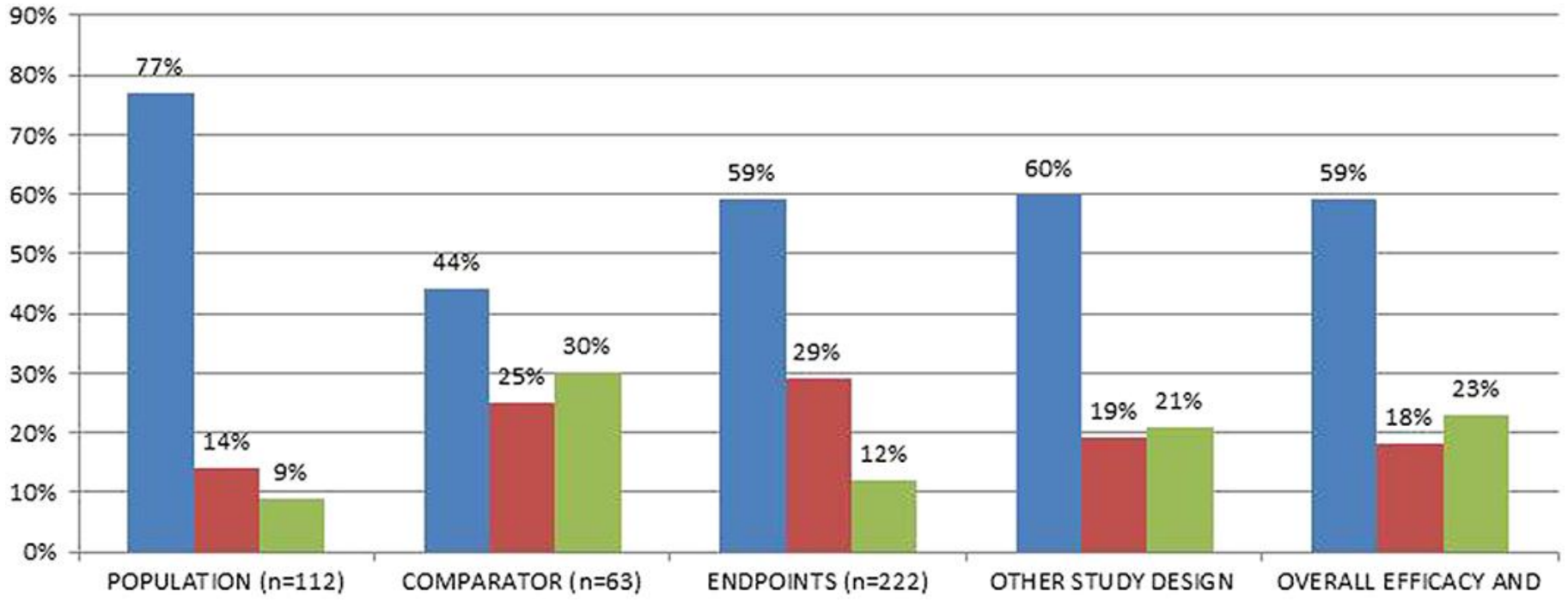
As of the 4th of July 2017 this initiative **replaces the parallel scientific advice procedure** by EMA and HTA bodies which required medicine developers to contact Member States' HTA bodies individually.

Best practice guidance for the parallel regulatory - HTA scientific advice procedure (EMA/502692/2015)

Replaced by

Guidance for parallel consultation (EMA/410962/2017)

How aligned are the perspectives of EU regulators and HTA bodies? A comparative analysis of regulatory-HTA parallel scientific advice



(based on 31 procedures). *n* represents the total number of HTABs expressing an opinion for each domain. full agreement partial agreement disagreement

British Journal of Clinical Pharmacology. Tafuri et al
Volume 82, Issue 4, pages 965-973, 1 JUL 2016 DOI: 10.1111/bcp.13023
http://onlinelibrary.wiley.com/doi/10.1111/bcp.13023/full#bcp13023-fig-0003

EU-level Advice Landscape

Regulator advice

- CHMP advice
  - HTA observers as option subject to EMA confidentiality undertaking

Parallel consultation

- Regulators and HTAS
- CHMP advice
- HTAS
  - PCC
  - PCI

HTA advice

- Consolidated
  - EMA as observers subject to EUnetHTA confidentiality undertaking

Eligibility criteria, Fees and Legal Basis are the same for EMA

New procedure EMA and EUnetHTA

The main benefits of the parallel consultation procedure include:

- **A Streamlined procedure** for Applicants;
- Increased opportunities for **mutual understanding and problem-solving ability** between EMA and HTA bodies through a more structured interaction;
- **Improved coordination** with, and **greater participation of HTA bodies** in parallel consultations through EUnetHTA's Early Dialogue Working Party (EDWP) and the EUnetHTA ED Secretariat.

This facilitates optimal and robust evidence generation for different stakeholders bringing benefits for patient access and public health.

Optimised development plan ➔ Improved access for patients

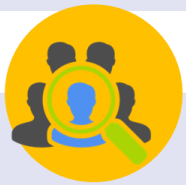
What is new / different?

New deadlines for submission of letter of intent and draft briefing doc

Single gateway for requests, simultaneous notification to EMA and EUnetHTA

Joint guidance and joint templates (letter of intent, briefing document)

Presubmission TC's only in exceptional cases



HTAB recruitment is done centrally by EUnetHTA ED Secretariat

EUnetHTA ED Secretariat is the point of contact in relation to all HTAB aspects

Two possible pathways: selection criteria applied by EDWP (consolidated or individual)

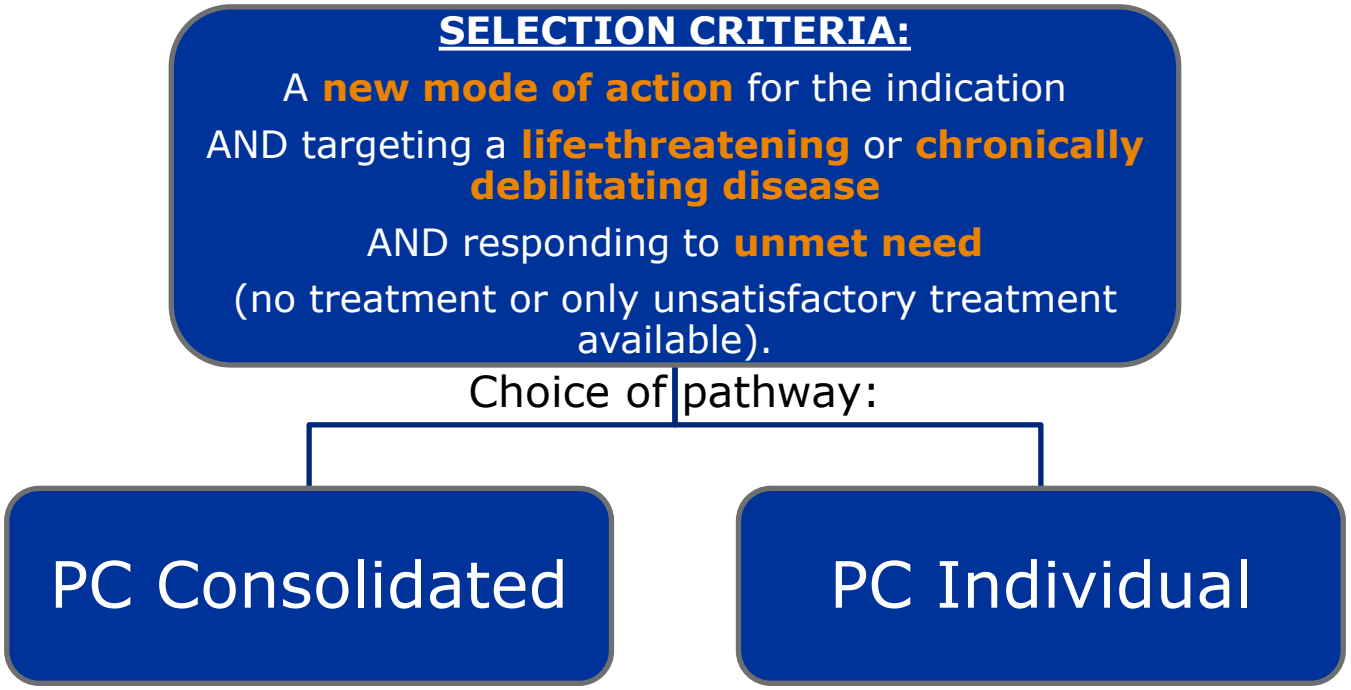
Possibility of more interaction between EMA and HTABs during the procedure

EUnetHTA Actors

EUnetHTA ED Secretariat	• Organisation and contact point • Acceptability of the Letter of Intent and all project management on the HTABs side. • HAS
Early Dialogues Working Party (EDWP)	• Is a standing committee established by EUnetHTA to ensure robust high-quality HTA outputs. • All EDWP members will participate in procedures selected for Consolidated PC.
The Early Dialogue Committee (EDC)	• Is constituted for a specific product and the members will fluctuate to a degree for each Consultation.
EDC Scientific Coordinator	• Undertakes scientific coordination on behalf of HTAs. • Facilitates discussion between HTABs in advance of meetings. • co-chair for the HTABs for the F2F meeting.

EUnetHTA: EDWP selection criteria

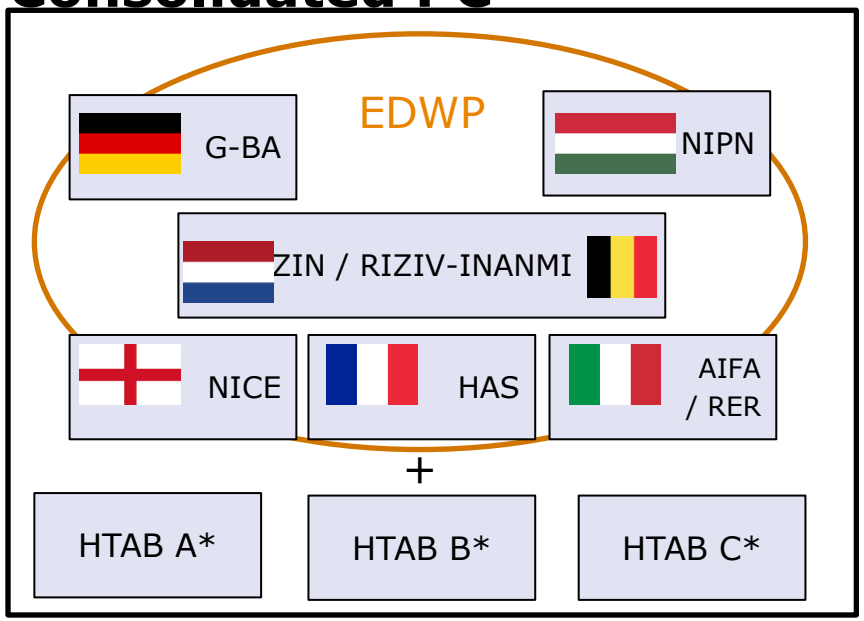
- The product should aim to bring added benefit to patients i.e. by:



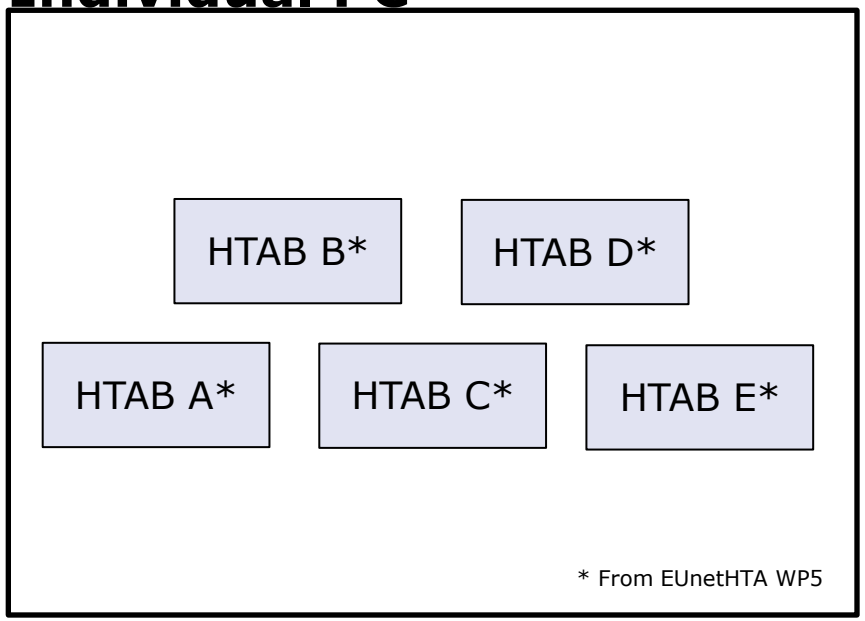
EUnetHTA: EDC

- For a specific product and the members will fluctuate to a degree for each Consultation.
- Composition (example) of the EDC for:

Consolidated PC



Individual PC



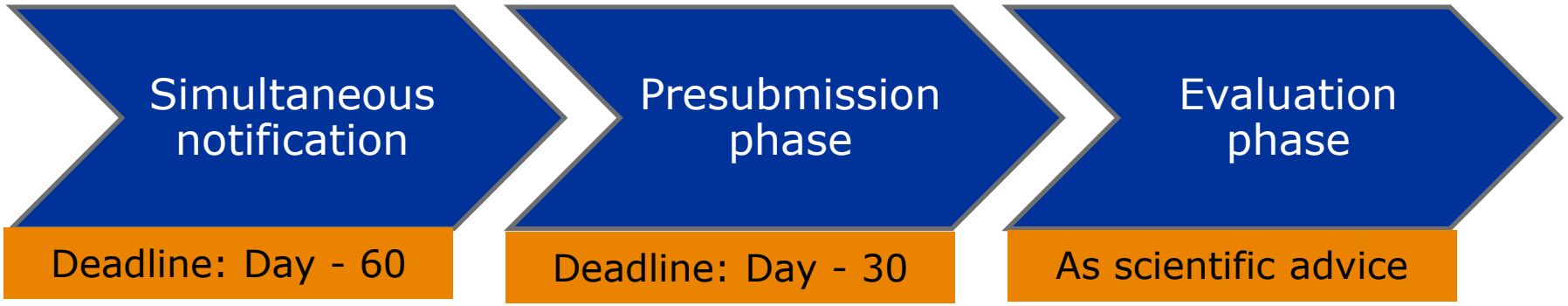
- The preferences of the Applicant (indicated in the Letter of Intent) will be taken into account, but participation of those HTABs cannot be guaranteed.

Composition of the EDWP as of July 4th 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)

PC – Consolidated vs Individual

	Parallel Consultations	
	Consolidated	Individual
HTAB recruitment	Centrally via EUnetHTA ED Secretariat	
Mode of participation of HTABs	Full EDWP and <=3 more	Voluntary HTAB participation
Selection criteria	Applies	Does not apply
Outcome	A single written report including: consolidated HTA written answers for shared positions, and individual HTA answers to those questions without consensus.	Individual HTABs provide HTABs' written reports

The process – 3 phases



Evaluation phase

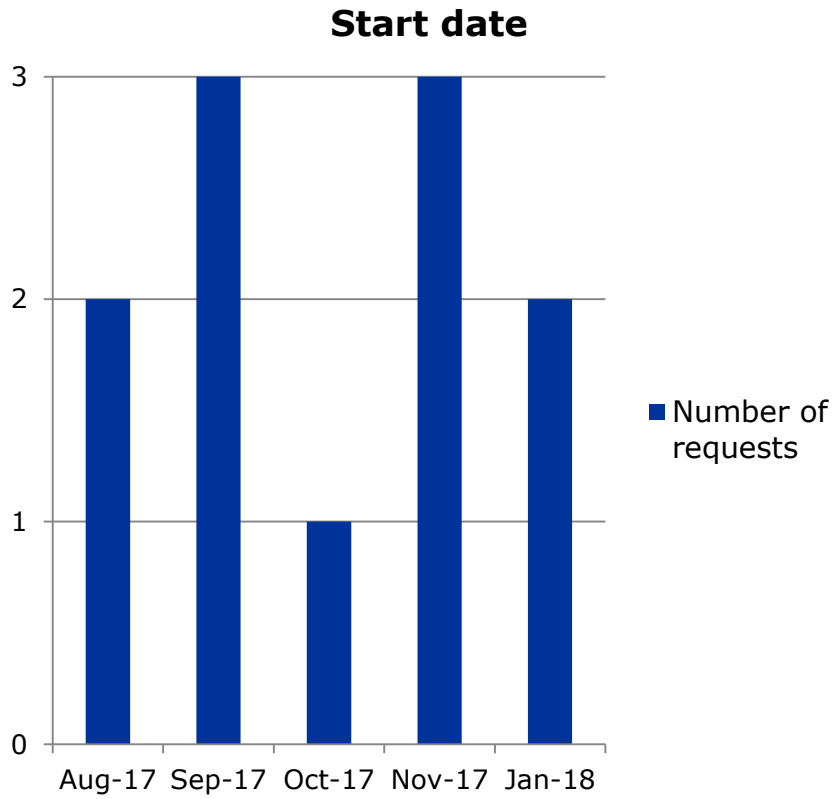
List of issues	Pre F2F TC	F2F meeting
• EUnetHTA ED Secretariat and EMA exchange Lists of Issues (LoI)	• To take place in the week after SAWP 2 • Identification and discussion of critical issues during the TC. If possible, try identifying possible solutions	• At the EMA premises, and will have 2 co-chairs. • **Tripartite session**: EDC, EMA and the Applicant. • The meeting duration will depend on the range of issues to be discussed and advice format 3-4 hours

Advice / outcome

Parallel Consultations		
EMA	EUnetHTA	
	Consolidated	Individual
CHMP final Scientific Advice/Protocol Assistance letter to the Applicant in accordance with the published timelines (i.e. the subsequent CHMP meeting).	EUnetHTA ED Secretariat sends final written answers to Applicant at ≈D +75.	Individual HTABs written answers to Applicant <=15 working days of the F2F.

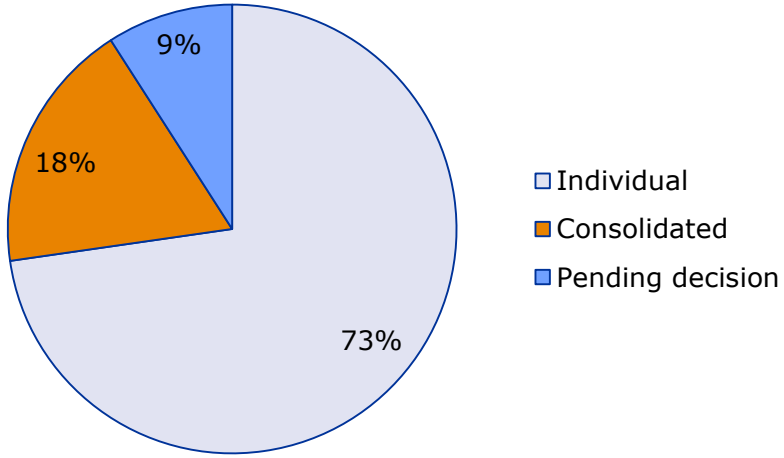
- Final outcome letters are exchanged between EMA and EUnetHTA ED Secretariat.

Experience of new procedure
Number of parallel consultations (PC) requests



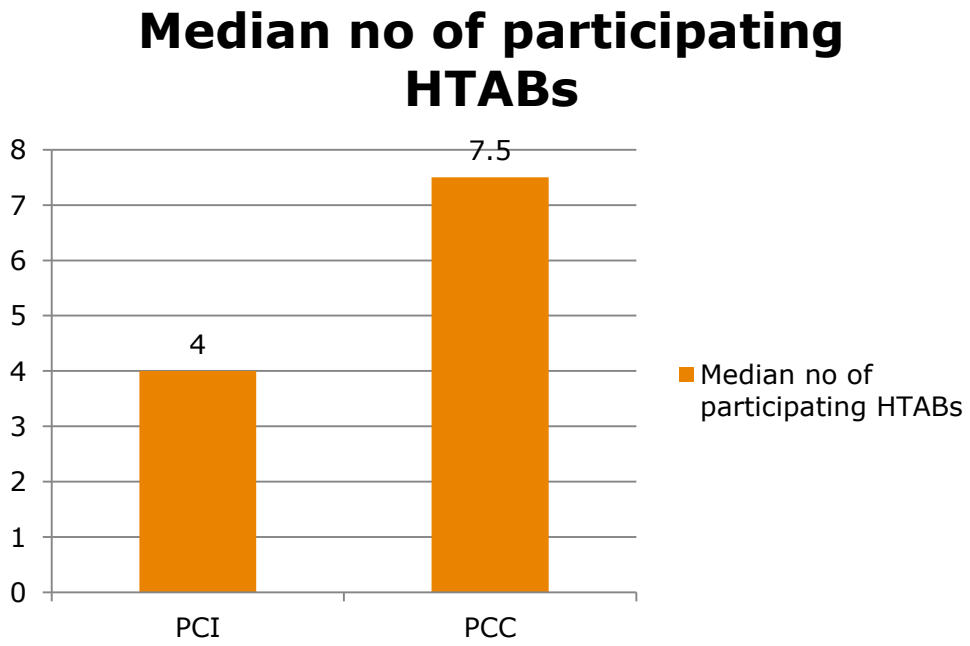
Total number of PC requests as of 10/11/2017: **11**

- Procedures started: 6
- Procedures finished: 2

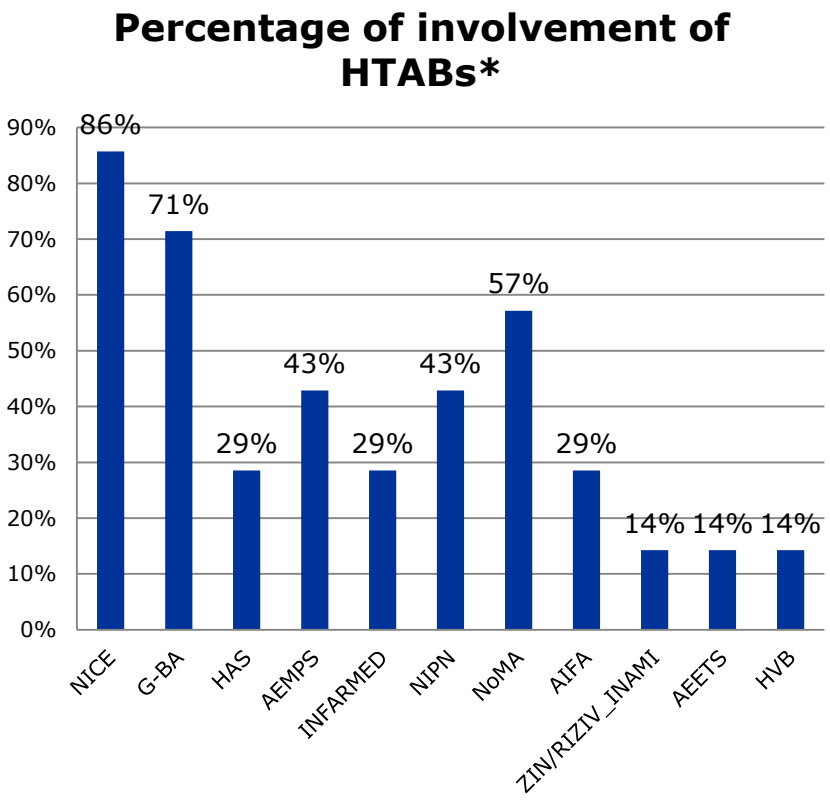


Features of requests in new procedure

- Mostly oncology indications 6, (dermatology, ophthalmology, metabolic, connective tissue)
- Patient representatives involvement in all 6 started procedures
- SME, Orphan and ATMP appear under-represented.



HTABs involvement (2)



*Numbers related to the 7 requests that have confirmed HTABs participants.

Total number of HTABs involved in Pc procedures: **11**

HTABs coordinators:

- AEMPS: 1 procedure
- HAS: 2 procedures
- NICE: 2 procedures
- G-BA: 2 procedures

Summary

Positive collaboration between EMA and EUnetHTA

- New platform, one gateway for all procedures for advice/dialogue
- 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
- 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

Key messages

- Platform for parallel discussion on initial evidence generation for MAA/reimbursement, and post licensing evidence generation
- Launched 03 July 2017- Early experience so far but positive
- More procedures /applications for parallel consultation encouraged - What are the barriers?

Acknowledgements
Inês Lucas
EMA, SAWP and
EUnetHTA colleagues

Thank you for your attention

Further information

Contact EMA scientificadvice scientificadvice@ema.europa.eu

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Additional information

- Documents and outcomes are exchanged throughout the procedure, if the Applicant provides consent in the letter of intent
- More interaction amongst stakeholders, since the beginning of the procedure, leading to a more efficient process:
  - Administrative TC
  - Pre F2F TC
  - Closed TC (Day 57)
  - Closed regulators/HTAB interaction during the F2F meeting
- Follow-up procedures
- Procedures ongoing