Industry Perspective on Advice Models

Where are we now, and where should we go?

Results of the EFPIA Industry Survey

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www.efpia.eu

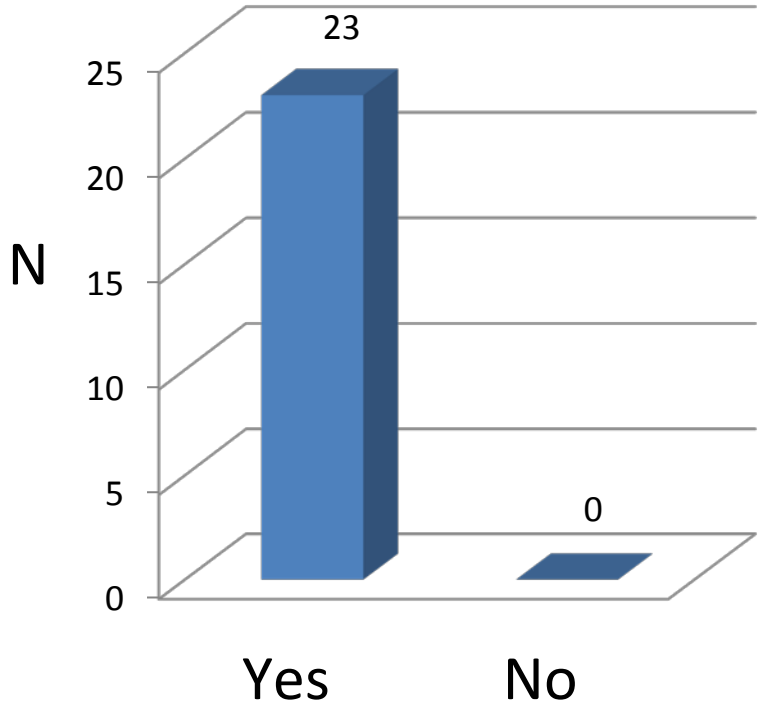
Respondents

- 23 respondents to questionnaire
  - 15 of top 20 Companies

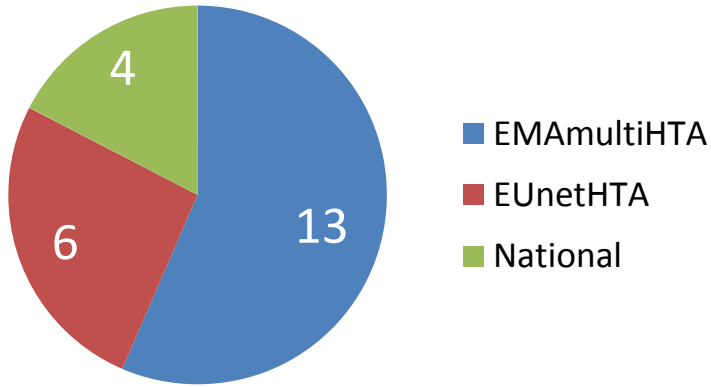
AbbVIE	AZ	Bayer	BI
BMS	Chiesi	Celgene	Daiichi
Ferring	GSK	Grunenthal	J&J
Lilly	Lundbeck	Menarini	MSD
Merck Serono	Novartis	NovoNordisk	Pfizer
Pharma.be	Sanofi	Viforpharma	

There is Demand from Industry for Early Advice

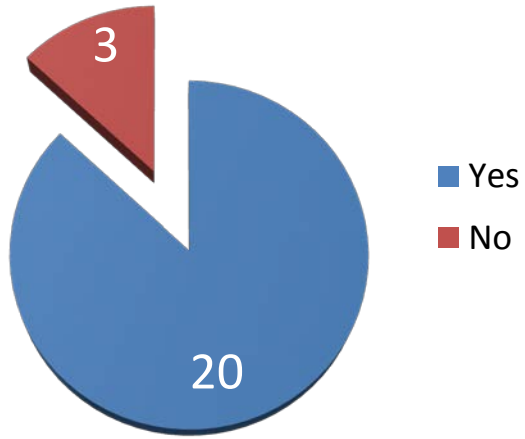
Is there a need for parallel regulatory HTA advice?



Preferred format



More than 1 format required?



What advice is wanted?

- Reason for seeking advice are multi-factorial
  - Indication, development stage, scenario & experiences
- Strong support for Parallel Advice option
  - Single Development Plan: Obtaining consolidated, parallel advice desirable
    - 'Ideally' - Consensus, joint, alignment,
- And a role for National HTA (& EUnetHTA) advice
  - local needs & requirements
    - Variations in methods, comparators, pricing policies, depth of discussion
- Advice Format is chosen on a case-by-case basis
  - Stage of development, issues to be addressed, timing
- Costs & resources also a consideration

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Requirements for Optimizing Parallel Advice

Strategically

- Focus on areas of issue / uncertainty to company
- Bridging of different requirements from Regulatory and HTA agencies
- Aim of alignment on realistic, achievable, requirements to optimise the development plan
- Timing – ideally pre-Phase III with option for pre-Phase II

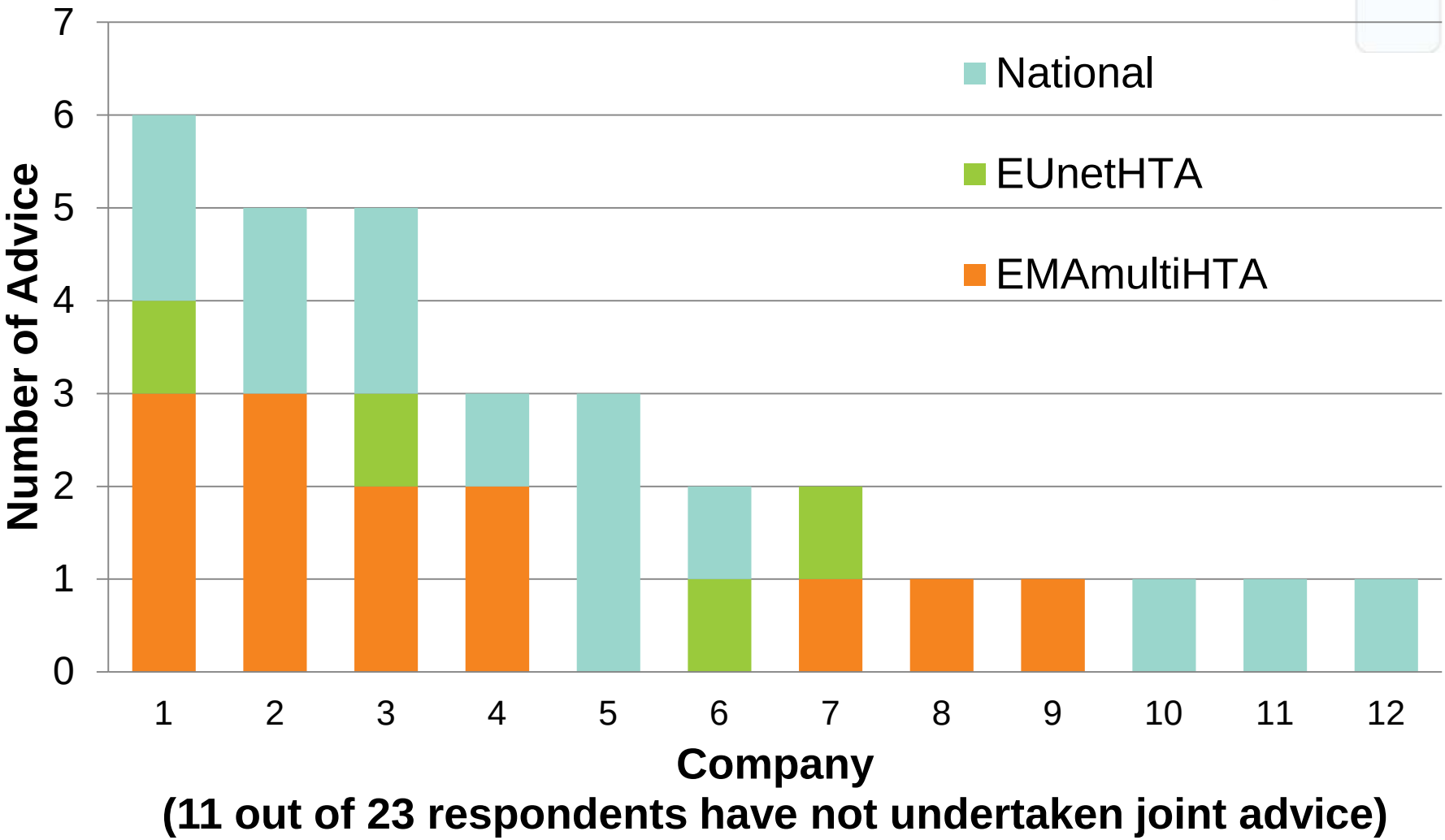
Practically

- Common procedures and timelines across Regulatory & HTA bodies
- Flexibility in choice of HTA bodies
- Simultaneous submission of common briefing documents
- Knowledgeable Experts from HTA bodies
- Representative number of HTA participants (3-5?)
- Equality of voice between stakeholders

Current constraints

- No clear owner of process
- Timing of engagement
  - Pre-phase II useful, but not all HTA's willing w/o phase II data
- Lack of guidance on timelines and expectations from all stakeholders
- Lack of familiarity from some HTA agencies with providing Advice
- No process for bridging divergences that are identified

Respondents Experience of Advice models



(11 out of 23 respondents have not undertaken joint advice)

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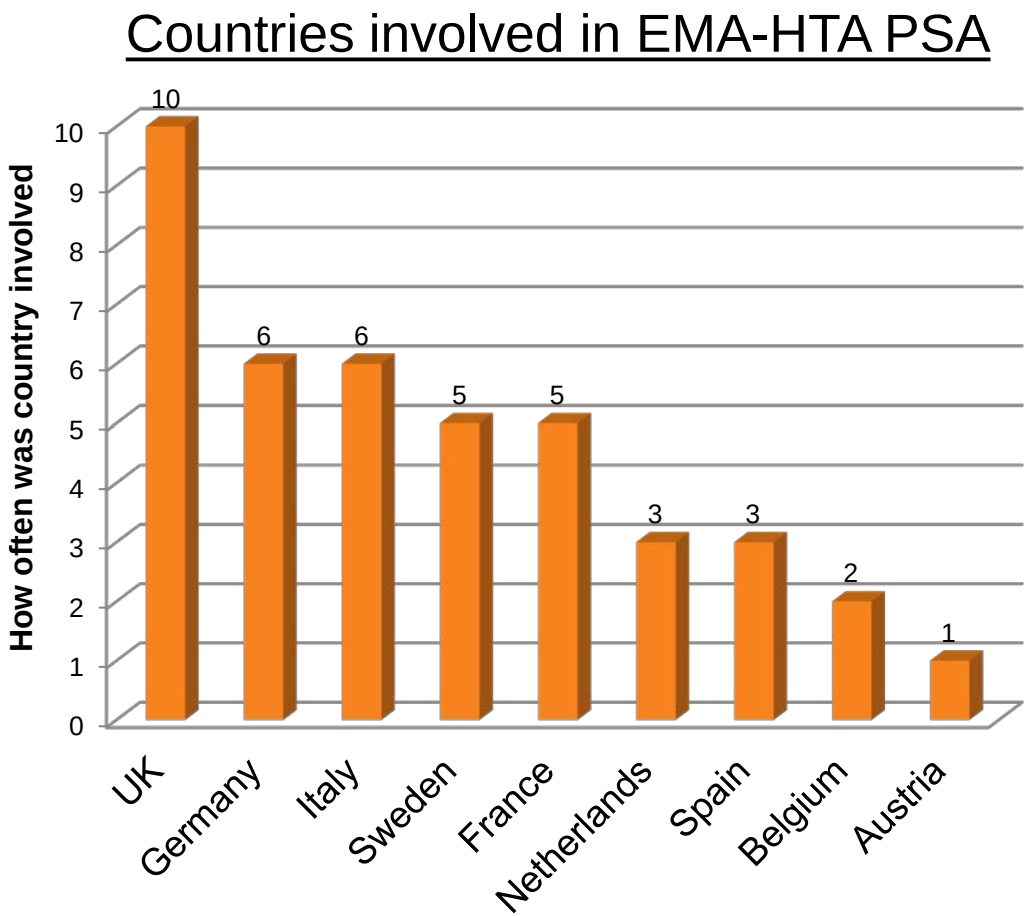
EMA multi HTA parallel scientific advice (PSA)

- 7 Companies have experienced EMAmultiHTA advice
  - Includes Tapestry
- A broad range of Countries have participated



*France was once involved as a silent observer and Belgium twice

Key Considerations of EMA-HTA Parallel Advice

Benefits

- One Collaborative discussion
- Input on which HTAs attend
- Commonality of issues discussed;
  - Comparators, end-points, PROs, Follow-up etc
- Simultaneous feedback
- Value in Regulators and HTAs hearing from each other
- Understanding of similarities & differences of stakeholder requirements

Areas for Improvements

- Sustainable process with clear owner
- More consistent & predictable HTA engagement
  - Attendance & Experience
- Appropriate time to allow discussion of issues arising
  - Identify alignment and discussion on differences
- Clear output from HTA advice needed: similar to CHMP SA letter

Future Interest in EMA-HTA PSA

- Most companies who expressed a preference, plan to use EMA-HTA PSA in next 2 years

- However, reasons for not seeking joint advice;
  - Limited perception of value of HTA advice in development teams
    - Eg: Lack of consensus among HTAs
  - Uncertainty on process
  - Time constraints
  - Lack of available resources

«complex development programmes with alternative scenarios may favour an initial regulatory advice followed by national HTA advice»

«overly broad approach in each case may not be optimal»

«Previously not needed – no expectation of mutually agreed regulatory/HTA programmes would be identified»

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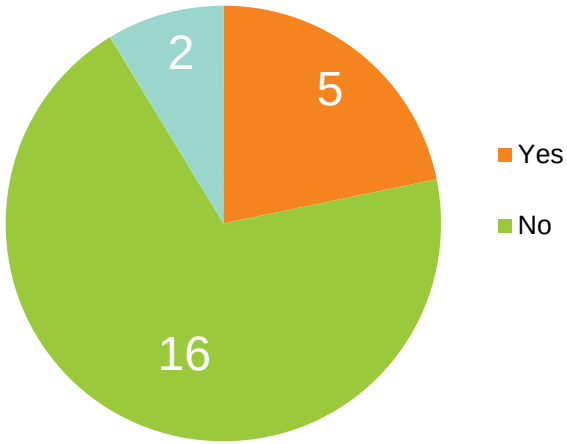
Encouraging further engagement in EMA-HTA PSA

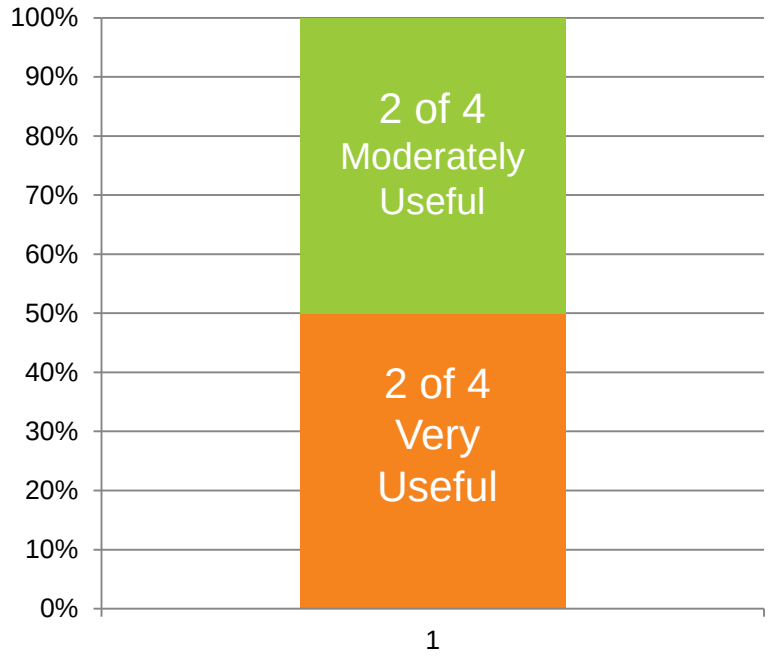
- Address areas for improvement
- Better communicate value of the procedure
  - workshops, forums, etc.
- Standardize, simplify and streamline the procedure
- Share more information on the value of the process
  Confirmation of non-binding and confidentiality of advice

EUnetHTA Early Dialogues

- Limited experience
- Only 4 Companies experienced EUnetHTA dialogue



- All engagements useful



Key Consideration of EUnetHTA Early Dialogues

Benefits

- One Collaborative discussion

  "receive consistent feedback on specific evidence development"

- Commonality of issues discussed;
  - Comparators, end-points, PROs, SoC, Follow-up etc
- Simultaneous feedback
- Understanding of areas of consensus and compromise between agencies

Areas for Improvements

- Lack of control/certainty of HTA attendees
  - May not address need
- Inconsistent expertise in agencies
- Lack of consistency on rules of engagement
  - Fee-for service v no fee acceptable
- Flexibility on timings (*pilots?*)
- Efficiency and time allocation to face to face meeting – *repetition*
- Insistence on closed questions
- Little discussion, more *'here is our view'*

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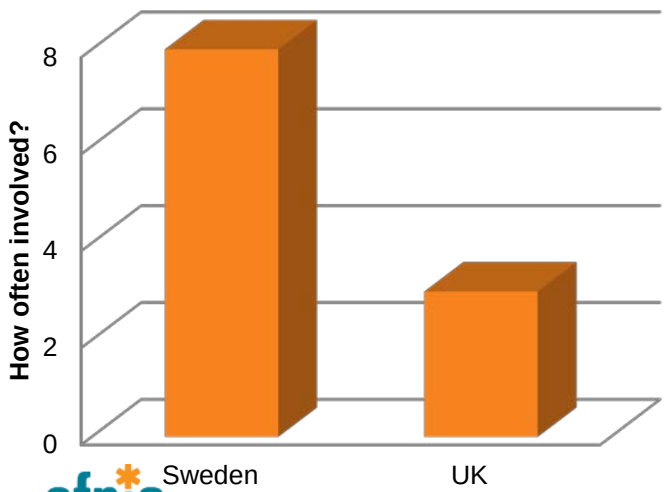
National parallel regulatory HTA advice

39 % of companies have experience with national PA:

Involved countries:



National Advice is relevant!

Main benefit: Addressing specific local (HTA) needs

- *NB: Not necessarily Parallel Advice*

Benefits

- Comfort with companies
  - most experience
- More open dialogue
- Commonality of issues discussed;
  - Comparators, end-points, PROs, SoC, Follow-up etc
- Simultaneous feedback
- Clarification on areas of consensus or compromise needed

Summary Points

- Sponsors request advice to improve development plans and deliver evidence to meet needs of multiple stakeholders
  - Where stakeholders have different preferences ideally a consensus is reached (eg for comparator, patient population)
  - Companies need to understand the implications of trade-offs
- All stakeholders are on a learning curve; need equity in input and engagement, and flexibility in approach
- Any parallel advice process needs to be;
  - Informed, Specific, Timely, Fit for purpose
  - Able to include appropriate clinical experts
  - Facilitate an open dialogue between stakeholders
- All advice should be confidential and non-binding
- PSA Processes need to be evaluated and evolve
  - This meeting is a good start, and will require further follow-up

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