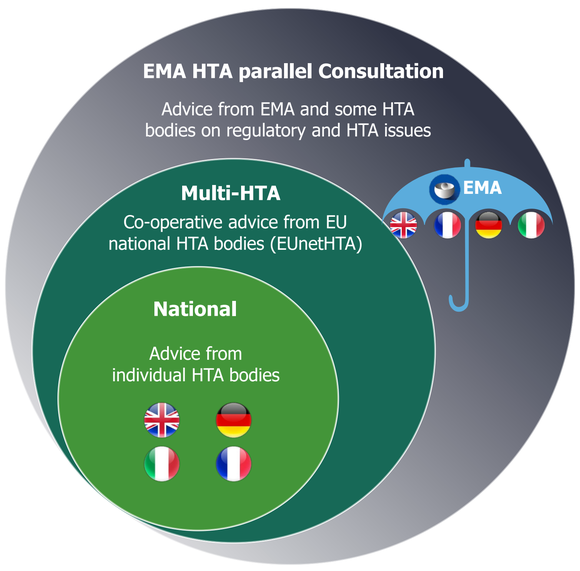
PHP303

WHAT ARE THE KEY CONSIDERATIONS FOR SEEKING PAYER SCIENTIFIC ADVICE IN THE EU?

Craddy P[1], Foxon G[2]
[1]Remap Consulting, Zug, Switzerland, [2]Remap Consulting, Cheshire, United Kingdom

Introduction/objective

- Within the EU, there are multiple HTA scientific advice options pharmaceutical companies can take to understand payers' clinical and economic HTA evidence requirements.
- These include single HTA, multiple HTA and EMA HTA parallel consultation; each with differing benefits, drawbacks, costs and complexities.
- The aim of this study is to compare the key aspects companies must consider when seeking HTA scientific advice within France, Germany, Italy and the UK (Figure 1).



Methods

- Secondary research was conducted to identify the HTA scientific advice processes at HAS (FR), G-BA (DE), AIFA (IT), NICE (UK), multi-HTA's early dialogue process and the parallel consultation with the EMA and EU HTA bodies.
- For the analysis we compared and contrasted between the following criteria:
  - Clinical and economic submission requirements
  - Scope of advice
  - Timelines
  - Fees
- The implications and resource considerations for manufacturers was determined.

Results

Figure 1: Table comparing payer scientific advice within HTA bodies across France, Germany, Italy and the UK

Criteria							
HTA body/submission requirement:	**HAS**	**G-BA**	**AIFA**	**NICE Office of Market Access**	**NICE scientific advice**	**Multi-HTA**	**Parallel consultations EMA, EU HTA bodies**
• Letter of intent/request form	■	■	■	■	■	■	■
• Acceptance/review of all submissions		■		■	■	■	■
• Briefing book	■		■		■	■	■
• Face to face meeting or Teleconference	■	■	■	■	■	■	■
Scope of advice:							
• Regulatory**	■		■		■		■
• Clinical	■	■	■	■	■	■	■
• Economic	■			■	■	■	■
Timelines	~24 weeks	~10-14 weeks	~18 weeks (up to 40 weeks)	~7-20 weeks	Light*: ~12 weeks Standard: ~36 weeks	27 weeks	~24-34 weeks
Fees	No Fee	~€2,000-€20,000	~€10,000-€40,000	~€17,000-€21,000 per face to face meeting	Light*: ~€17,000 Standard: ~€46,000-€63,000	Dependent on HTA bodies participating	~€43,000-€86,100 EMA + respective HTA fees

Notes:
*Applies to SME status (Small, Medium Enterprises).
**Italy, France and NICE regulatory advice is with local regulatory body

Discussion and conclusion

- **Submission Requirements**: The G-BA require the fewest submission materials. In contrast the EMA, NICE, HAS and AIFA require a comprehensive book, list of questions and company position for each question to be submitted prior to meetings.
- **Scope of Advice**: The G-BA provides relatively defined feedback, such as likely comparators or patient populations, whereas NICE also provides feedback on statistical analysis and health economic considerations. The EMA HTA parallel consultation also offers regulatory guidance, but may not provide the depth of feedback compared with individual HTA consultations.
- **Timelines**: The G-BA and NICE's Office of Market Access have the shortest timelines, providing advice within ~7-14 weeks. NICE's scientific advice and EMA HTA parallel consultation take between 18 and 34 weeks.
- **Fees**: Cost of seeking advice varies considerably. HAS does not request a fee, whereas EMA HTA parallel consultation incorporates fees from the EMA and each HTA involved in parallel consultation, can exceed €50,000.
- **Conclusion**: This research highlights the variability regarding the scientific advice submission processes and scope of advice provided across the EU. Pharmaceutical companies should give careful consideration as to which procedure is most appropriate for their needs, taking into account their timelines and resources and the type of payer insights required to optimise their clinical trial designs from an HTA perspective.

ISPOR EU 2018, 10-14 November 2018, Barcelona, Spain