Similarities and differences in early scientific advice processes

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OBJECTIVES

In recent years, many pharmaceutical companies have increasingly focused on optimising clinical development programs not only to the demands of the regulators, but also to health technology assessment (HTA) bodies (HTABs), and payers. Consequently, **there has been an increase in early scientific advice (ESA) processes involving HTABs and regulatory bodies**.

The objective of this study was to r**eview ESA processes involving HTABs in the United Kingdom (UK), France, and Germany** as well as the **parallel EMA/EUnetHTA21 joint scientific consultation (JSC) process** and evaluate similarities and differences between these.

METHODS

A review of ESA processes in the UK, France, Germany and JSC was performed. **Each process was evaluated in terms of regulatory agency participation and the UK, France, Germany and JSC processes were contrasted to highlight differences and similarities according to the following key attributes**: year of introduction, timeline, language, eligibility criteria, timelines, fees, attendees (i.e., external expert involvement and patient involvement) and the scientific topics for discussion.

RESULTS

The processes in the UK, France, Germany and the JSC process have similarities and differences in the characteristics. The most striking differences relate to the fees for engagement, the duration and outcomes of meetings, the scientific topics addressed and the extent of stakeholder involvement.

Companies can select scientific advice processes following broadly the following five strategies:

1) single-country HTAB,

2) single-country HTAB and regulators,

3) multi-country HTAB,

4) parallel JSC with HTAB and regulators,

5) regulators only.

Prospective and timely parallel JSC with HTAB and regulators may allow the company to integrate HTA and regulatory needs into the development plan and fulfil the evidence requirements of both regulators and HTA bodies at the same time.

Currently, the 2nd Open Call for JSCs is closed and 5 medicinal products have been selected. A next call has not been announced yet.

CONCLUSION

- **The number of integrated scientific advice processes has increased in recent years. Manufacturers value the opportunity to test and optimise their clinical development plans to meet regulatory and HTABs requirements to facilitate reimbursement.**
- **Selecting an appropriate early scientific advice process depends on the strategic objectives of the new product and the specific regulatory and HTA complexities for the therapeutic area.**
- **Parallel JSC with HTAB and regulators might offer a unique opportunity for multinational parallel product strategies however current availability is limited.**

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Comparison of ESA processes in UK, Germany and France and the parallel JSC in the EU

Country	HTA body	Year of intro-duction	Language	Eligibility criteria	Timelines/ Duration	Fees	Attendees	Scientific topics for discussion						
								Overall study design	Compara-tors	Endpoints and their definitions	PRO specifically	Indirect treatment comparison	Economic assessment / Modelling	RWE
UK	NICE	2009	English	No advice on generics and biosimilars, new formulations of existing products (unless for new indications) and anti-HIV medicinal products	Consultation 12 (express) to 18 (standard) weeks following submission of documents	£60-75K (NICE to provide quote after submission of draft briefing book)	pC: unlimited panel includes clinical, health economic, patient and HTA specialists	✓	✓	○	○ EQ-5D primarily	✓	✓	✓
Germany	G-BA	2011	German or German summary + English briefing book as attachment	No advice on closed HTA or legal procedures	Consultation 10 weeks following submission of documents	€10K (exact fee based on scope of questions and increases with involvement of regulatory authorities)	pC: unlimited joint advice with BfArM or PEI possible	✓	✓	✓	✓	x	x	○
France	HAS	2010	LOI in French, Briefing book in French or English	New MoA, high unmet need, timing of advice before pivotal trial protocol is finalized; HAS determines eligibility	Consultation 90 days following submission of documents	Free	pC: unlimited experts and patients may be invited by HAS; Members of appraisal committees cannot participate	✓	✓	✓	✓	✓	✓	✓
EU	JSC	2022	English	Clinical trial (pivotal phase II/ or III) has not yet started; Unmet medical needs; First in class; Potential impact on patients, public health, or healthcare systems; Significant cross-border dimension; Major Union-wide added value; or Union clinical research priorities	F2F meeting 60 days after submission of documents	From €46,900 to €94,000	pC: 12 – 14** EUnetHTA 21 Assessor, EUnetHTA 21 Co-Assessor and a minimum of 6 CSCQ JSC member HTABs	✓	✓	✓	✓	✓	✓	✓

*Note: NICE does prioritize technologies that address healthcare system needs due to current resourcing constraints, **Note: Potentially and in case of applicants between collaborating companies
✓= Topic is covered, ○ = Topic is partially covered, x = Topic is not covered

Abbreviations: BfArM: Bundesinstituts für Arzneimittel und Medizinprodukte; CSCQ: Committee for Scientific Consistency and Quality; EMA: European Medicines Agency; EU: European Union; ESA: Early scientific advice; EUnetHTA 21: European Network for Health Technology Assessment 2021; F2F: Face to face meeting; G-BA: Gemeinsamer Bundesausschuss, HAS: Haute Autorité de Santé; HTA: Health technology assessment; HTAbs: Health technology assessment bodies; JSC: Joint scientific consultation; LOI: Letter of intent; MoA: Mode of action; NICE: National Institute for Health and Care Excellence; PEI: Paul-Ehrlich-Institut; PRO: Patient-reported outcomes; pC: Pharmaceutical company; RWE: Real world evidence; UK: United Kingdom

Sources: IQVIA HTA specialists' interview, Information available on https://www.nice.org.uk/about/what-we-do/life-sciences/scientific-advice/, https://www.g-ba.de/themen/arzneimittel/arzneimittel-richtlinie-anlagen/nutzenbewertung-35a/informationen-fuer-unternehmen/, https://www.has-sante.fr/jcms/c_2623726/en/guidance-for-national-early-dialogues-on-medicinal-products and https://www.eunethta.eu/jsc/