Early Scientific Advice in Europe: An Overview of Processes and Requirements

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INTRODUCTION

- Early scientific advice (ESA) comprises a systematic process through which national Health Technology Assessment (HTA) bodies provide manufacturers with guidance on their clinical development strategy.[1]
- Early stakeholder engagement aims to improve the quality of evidence to be submitted, hence, to optimize market access strategy.
- The purpose of this study was to describe the main features characterizing these procedures in scope European countries.

METHODS

The national HTA websites of eight European countries (Denmark, France, Germany, Italy, Norway, Spain, Sweden, United Kingdom) were reviewed and key information on processes, timelines, and costs was summarized.[2-9]

RESULTS

- Across **all** countries national authorities offer a scope of services allowing pharmaceutical companies to request information pertaining to the HTA process.
- Advice is **not legally binding** for any of the participating parts and in most cases, applicants are provided with an analytical description of the process and application forms.
- In Denmark, Norway, and Sweden this procedure is **not separate from regulatory scientific advice** and is offered as joint consultation supplementing discussions with regulatory entities.
- Timelines range from nearly 40 (Norway) to 110 days (France).
- Compensation also varies greatly from 4,400€ (Spain) to 69,000€ (UK), while in Norway and France there is no fee.
- The French agency (HAS) engages in early dialogues **only with manufacturers developing innovative products, targeting an unmet need.**
- In the UK, NICE, apart from set scientific/economic consultation on upcoming trials, also provides parallel scientific advice with the Canadian Agency for Drugs and Technology in Health (CADTH) and has also established **Preliminary Independent Model Advice (PRIMA),** a peer review service focused on the quality of health economics models.
- Only in the UK **patient experts** participate in the early advice meetings.

Table 1. Summary of key features of early scientific advice processes

Country	ESA	Timeline (days)	Cost ¥	Patient engagement
	✓*	60	4,700€	-
	✓	110	No fee	-
	✓	50	18,000€	-
	✓	90	15,450€	-
	✓*	40	No fee	-
	✓	90	4,400€	-
	✓*	N/A	5,800€	-
	✓	105	69,000€	✓

¥ Costs were adjusted and converted to 2022 Euros.* Not separate from regulatory scientific advice. Abbreviations: ESA, Early Scientific Advice

CONCLUSIONS

- Early scientific advice scope, practices and costs vary greatly across different European settings.
- Further patient involvement will add value and enrich discussions in HTA scientific advice procedures.

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Presented at ISPOR 2023 | Boston, MA, USA | 7–10 May 2023

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