Comparison of Early Scientific Advice Processes in UK, France and Germany (HTA Only): Tips and Tricks

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Background
• Globally, pharmaceutical companies are able to obtain scientific advice (SA) from regulatory agencies, such as the Food and Drug Agency and the European Medicines Agency (EMA), to enhance their clinical trials and maximise their chances to obtain regulatory approval. In recent years, particularly in Europe, a paradigm shift in the Health Technology Assessment (HTA) environment has led to an increase in the integration of requirements of HTA bodies and payers in terms of design and methodology into clinical development programmes (CDPs) which has resulted in increasing importance of obtaining SA from HTA bodies, as well as from regulatory agencies.1
• To de-risk CDPs and to provide relevant data for the demonstration of clinical and economic value, manufacturers may seek early SA from HTA agencies such as National Institute for Health and Care Excellence (NICE) in the UK, French National Authority for Health (HAS) in France and the Federal Joint Committee (G-BA) in Germany2 (Figure 1).
• SA can provide manufacturers insight regarding HTA bodies’ current thinking regarding design and methodology of CDPs. Companies may seek advice at different stages of development from as early as Phase 1 through Phase 4.1
• However, challenges have emerged and companies seeking single country early SA have to face a diverse and complex environment with country-specific processes, methodologies and requirements.

Objectives
• The aim of this study is to compare the three most widely used single early SA processes offered by NICE (UK), HAS (France) and G-BA (Germany).

Methods
• This overview and suggestions are based on reviews of NICE, HAS and G-BA SA processes and requirements as well as authors’ expertise. Authors reviewed the SA processes, timelines, template availability, and role of each participating party.

Results
• Timelines for SA vary from two to five months.
• Costs range from nothing to £50,000.
• The G-BA has the shortest process timelines of the three.
• It is highly advised to start the process as early as possible to obtain the most benefit.
• The advice is not legally binding for any of the processes, however, the received guidance provides valuable insights on the choice of comparators, endpoints, study design and health economics.
• NICE and HAS provide briefing book templates, while G-BA provides a request form.
• Questions included in the briefing book may cover a range of topics to help companies de-risk their clinical development programmes.
• NICE and HAS evaluate cost-effectiveness, while G-BA only discusses clinical benefit.
• SA is country- and payer-specific and helps to build relationships between all parties.

Conclusions
• Though limited, empirical data suggest that compliance with the advice given may increase the likelihood of a positive appraisal.
• Companies planning to seek reimbursement of new medicinal products in the UK, France, or Germany should consider developing robust HTA SA programmes early in the clinical development process to maximise the value of the advice received from these HTA bodies.

References
5. Mapi is an ICON plc company.
6. Mapi is an ICON plc company.

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