Early Dialogue With NICE and EUnetHTA: A UK Perspective in a Politically Uncertain Era

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BACKGROUND

- Health Technology Assessment Bodies (HTABs) are instrumental in decision making regarding the reimbursement of pharmaceuticals or recommendations for their use in health care systems. HTABs across Europe may require different levels and types of evidence in order conduct a health technology assessment (HTA).
- The National Institute for Health and Care Excellence (NICE) in the United Kingdom (UK) and the European Network for Health Technology Assessment (EUnetHTA), a network of HTA bodies, including the UK, offer manufacturers the opportunity to engage in early dialogue (ED) regarding specific evidence requirements for products in development. Recommendations inform evidence generation within and outside the clinical programme for future HTA product submissions.

OBJECTIVE

- This review compares HTA ED processes offered by EUnetHTA and NICE, provides information on good quality interactions for manufacturers, and describes new service options introduced by NICE, including contingency plans should the UK leave the European Union (EU).

METHODS

- A targeted review of literature and Internet-based sources identified the most recent information on ED processes provided by NICE and EUnetHTA. Both offer joint regulatory and HTA advice; this review focused on the HTA advice process for pharmaceutical products.

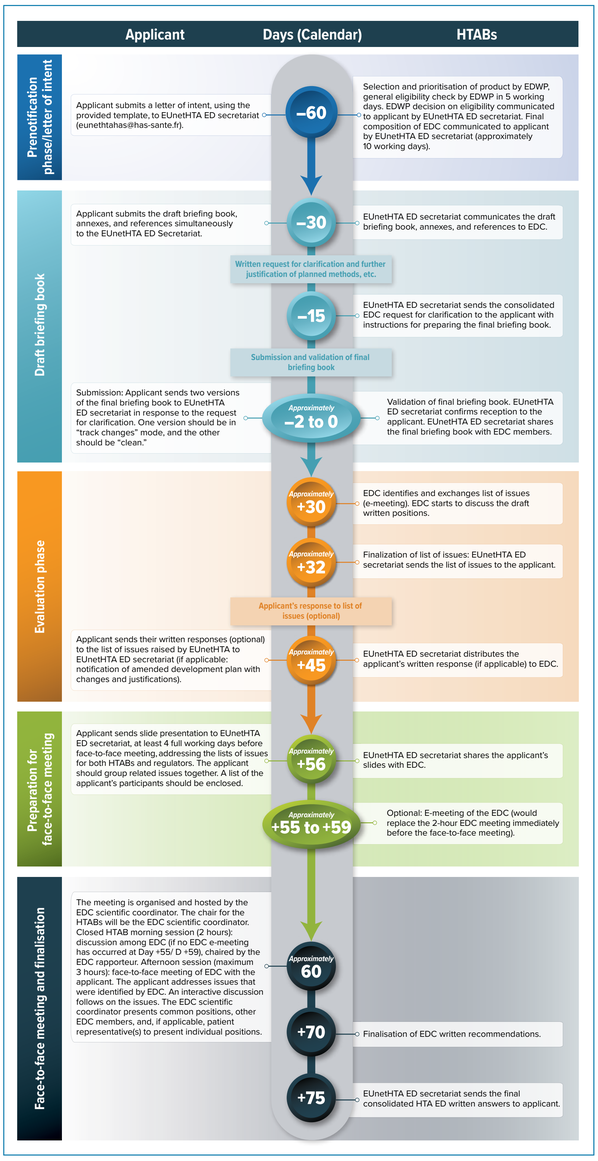
RESULTS

- The EUnetHTA ED process involves the ED Working Party (EDWP) with agencies from France, Germany, Hungary, Italy, UK, Belgium, and The Netherlands; additional HTA bodies may participate in EDs as required.[1]
- Countries that are not members of the EDWP are routinely invited to participate in EDs. The final group of HTA bodies participating in a specific ED will comprise the ED Committee (EDC). The EDC is composed of the EDWP and any other participating HTA bodies.[1]
- Figure 1 outlines the EDWP and EUnetHTA partner organisations.
- Manufacturers submit a briefing book with product and disease information plus specific questions on clinical and economic issues for HTA. EUnetHTA and NICE include the opportunity for face-to-face discussion and written recommendations.

Figure 1. EUnetHTA Core Countries and Expanded List

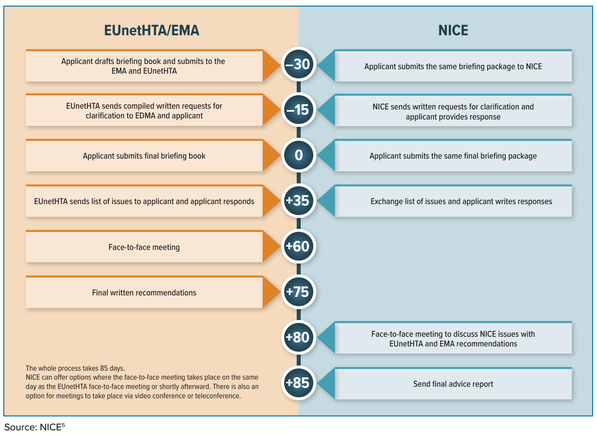
EUnetHTA Process

Figure 2. Process for EUnetHTA Early Dialogue



Source: EUnetHTA: Procedure description for EUnetHTA Multi-HTA Early Dialogues for Pharmaceuticals. 2019: Available at: https://www.eunethta.eu/wp-content/uploads/2018/03/Multi-HTA-Pharma-Procedure_180227.pdf. Accessed 5 September 2019.

Figure 4. NICE Scientific Advice Concurrent European Service



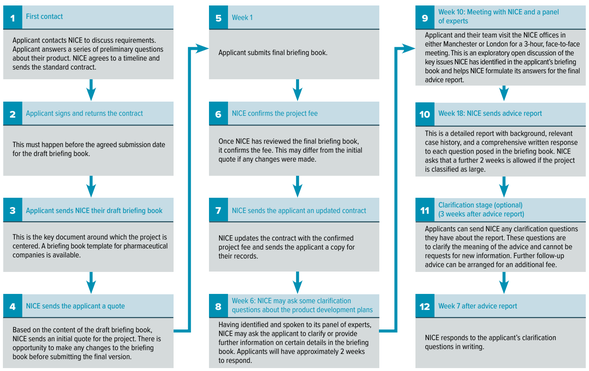
Source: NICE[5]

NICE Process and Services

- NICE employs a similar overall process and in April 2019 introduced different options, including an express service, a choice of more limited expert review, and opportunities for parallel consultation with other payers.

Standard Advice

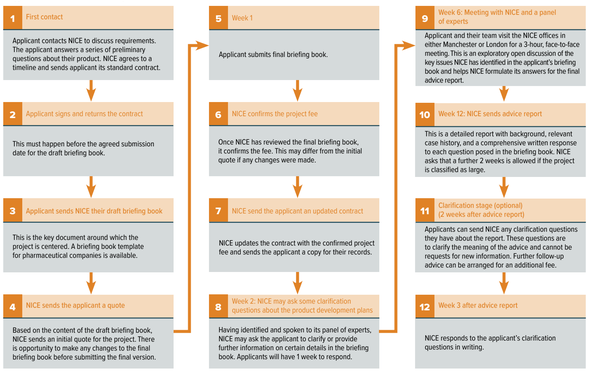
Figure 3a. NICE Standard Advice



Source: NICE[3]

Express Advice

Figure 3b. NICE Express Advice



Source: NICE[3]

PRIMA

- NICE also offers a service that looks specifically at the economic model. The Preliminary Independent Model Advice (PRIMA) service aims to provide expert independent advice to improve the quality of health economic models.
- The service includes independent expert advice, identification of any flaws in structure or coding and advice on the transparency and usability of the model.

Source: NICE: PRIMA[4]

Parallel Advice With Other Payers

- NICE has set up collaboration with the Canadian HTA (Canadian Agency for Drugs and Technologies in Health) to provide joint advice.
- Opportunities are available for joint advice with Blue Cross Blue Shield (United States) and FINOSE (Norway, Sweden, Finland).

Brexit

- NICE has published steps to ensure continuity of service if the UK leaves the EU. Where NICE is part of a joint EUnetHTA ED, all existing contracts will be fulfilled, and NICE will provide its own advice letter and a NICE-specific face-to-face meeting. NICE has put a contingency plan in place to enable advice to be sought concurrently with advice being sought from the European Medicines Agency (EMA) or EUnetHTA.

CONCLUSIONS

- EUnetHTA and NICE ED services have similar process structures but differ in breadth of country feedback and flexibility of scope and timelines.
- The optimal time to seek ED is before initiation of main registration efficacy studies, aiding appropriate study design for HTA and regulatory review; this is the time at which the manufacturer will gain the most benefit from the ED process.
- Alternatively, ED sought during study conduct informs the approach to economic analysis.
- If the UK leaves the EU, NICE has published contingency plans for continuity of service.

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