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. A collaborative process is essential to gather evidence from multiple HTABs.
- EUnetHTA is the European Network for Health Technology Assessment, a network of HTA bodies across Europe, with the purpose of harmonizing HTA processes and results.
- NICE (National Institute for Health and Care Excellence) is a UK-based body that provides independent guidance on the use of drugs, medical technologies, and other health care services.

OBJECTIVE

- This review compares HTA processes provided by NICE and EUnetHTA, highlighting differences and similarities in their methodologies and processes.

RESULTS

1. **EDWP** process overview:
   - EDWP (Early Dialogue With NICE) process involves the ED Working Party (EDWP) with agencies from France, Germany, Hungary, Italy, the UK, Belgium, and The Netherlands. It includes a pre-call in EDs as required.
   - Participants are the representatives of the HTABs invited to participate in EDs, including NICE, the first HTA body participating in a specific ED with the ED Committee (EDC).

2. **NICE** process overview:
   - NICE has published steps to ensure continuity of service if the UK leaves the EU. Where NICE is part of a joint advice with EUnetHTA, the EDWP, or ED processes provided by NICE and EUnetHTA, both offer joint regulatory and HTA advice.

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.

CONCLUSIONS

- EUnetHTA and NICE ED processes have similar process structures but differ in breadth of evidence generation and flexibility of scope.
- The optimal time to seek ED is before radiation of main registration efficacy studies, aside from appropriate study design for HTA and regulatory review.
- A targeted view of NICE processes offered by EUnetHTA and EMA provides information on post-authorization side effects for manufacturers, and describes new service options introduced by NICE, including contingency plans should the UK leave the European Union (EU).

REFERENCES

- EUnetHTA. Procedure for EUnetHTA Multi-HTA Early Dialogues for Pharmaceuticals. 2019. Available at: https://

CONTACT INFORMATION

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