Differences in evidence requirements of HTA authorities in UK, Italy, Netherlands, Poland, Portugal, and Sweden to appraise new products

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Objectives: One of the reasons that the national timeline to appraise new products gets extended are rejections during the HTA process. The methodological guidelines for assessment have been developed in order to harmonize the HTA process. However, there are still many variations between HTA agencies. The aim of this study is to identify differences in evidence requirements of HTA agencies in European countries.

Methods: A literature search in the PubMed and Cochrane databases undertaken in May 2022 resulted in the identification of relevant publications. The findings on the differences in evidence requirements of HTA agencies in six European countries (UK, Italy, Netherlands, Poland, Portugal, and Sweden) are included in the subsequent analysis.

Results: The level of alignment is highest for the use of biomarkers and RWE. These in Portugal. England and Italy determine acceptance on a case-by-case basis. elements are "often accepted" by all HTA bodies. The level of alignment is lowest when HTA bodies are asked for acceptance of surrogate endpoints other than progression-free survival (PFS). Every agency looks at the use of surrogate endpoints differently: these are accepted in Poland and often accepted in Sweden; not accepted in the Netherlands and often not accepted

Conclusion: The HTA challenges are mainly based on the methodological guidelines. Therefore, the conventional HTA methodologies may need to be adapted, mostly in terms of pharmacoeconomic evaluation.

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