Multi-Country HTA Initiatives versus National HTA Processes: The Optimal Reimbursement Strategy

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ISPOR Poster Acceptance Code: HTA43
Abstract ID: 122193

Introduction

Health technology assessment (HTA) plays a crucial role in the reimbursement decision-making process in many countries. Although HTA frameworks typically share a similar goal (i.e. to evaluate the value of medical treatments and products and publish guidance on the appropriate use of technologies), recommendations vary widely throughout jurisdictions, even for the same drug (1).

To harmonise methodological standards and foster collaboration among European HTA bodies, several joint HTA initiatives have been established over the past years.

Objectives

This review aimed to provide a concise overview and comparison of joint European HTA and drug price collaborations and to gain an understanding of how these impact pricing and market access.

Methodology

- A targeted literature review was conducted to identify active multi-country HTA and pricing initiatives
- Information was retrieved from healthcare authority websites, peer-reviewed articles, and grey literature
- A qualitative analysis compared the scope, objectives, member countries, process requirements, number of therapies reviewed, and final decisions across the initiatives
- The literature search was limited to the English language

Results

The current review identified seven active large European multi-country collaborations. All initiatives aim to improve market access and most have a particular focus on expensive, innovative medicines. Their scope, however, differs and may encompass horizon scanning, joint HTAs, joint pricing and reimbursement negotiations, and/or information sharing (Table 1). In addition to these, the PPRI and EURIPID databases aim to increase transparency in medicines' prices across Europe but have an informal nature and were, therefore, excluded from our review.
EUnetHTA was identified as the largest joint HTA initiative, comprising of 30 countries; it achieved the most noteworthy results to date.

To build on the achievements and lessons learnt from the EUnetHTA Joint Actions and support the continuation of EU cooperation on HTA, the EUnetHTA21 joint consortium was launched in 2021. The European HTA regulation will be adopted in a stepwise approach, starting with bridging activities that will allow for evolving and strengthening of the methodological basis for European HTAs. From 2025 onwards, all new cancer medicines and advanced therapy medicinal products will be jointly assessed; orphan medicinal products will also be considered from 2028. However, while countries are requested to take EUnetHTA assessments into consideration, the final appraisal as well as pricing and reimbursement decision remains with the national bodies (2).

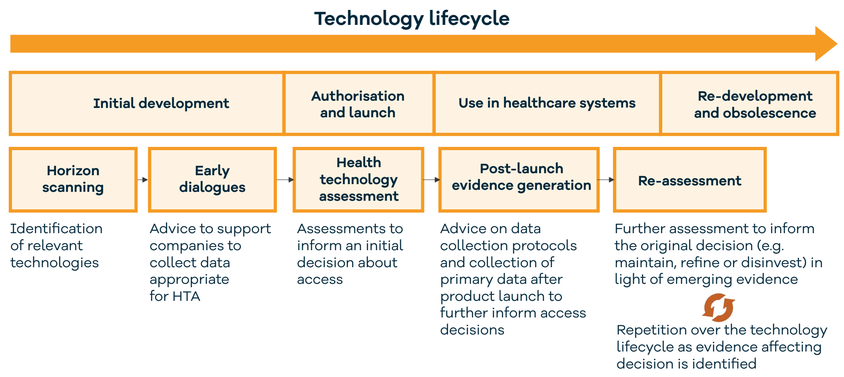
Table 1. Large EU multi-country collaborations identified during our review

Joint HTA initiative name	Countries involved	Established in	Scope	Key focus areas/activities	Outcomes/developments
EUnetHTA	N=30 Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Ukraine, United Kingdom	2006	New technologies	• Early dialogues • Joint and collaborative assessments • Post-launch evidence generation	66 collaborations across all activities listed
Baltic Procurement initiative	N=3 Estonia, Latvia, Lithuania	2012	Medicines & medical devices (lending) & vaccines (joint procurement)	• Joint procurement & information sharing of vaccines and medicines • Sharing of medicines across countries in times of shortage	• Joint procurement of 3 vaccines • Lending agreement for centrally procured medicines
BeNeLuxA	N=5 Belgium, Netherlands, Luxemburg, Ireland, Austria	2015	Mainly new & costly medicines	• Horizon scanning • Health technology appraisals • Pricing & reimbursement negotiations • Exchange of strategic information	• International Horizon Scanning Initiative (2019) • 7 joint HTA procedures
Nordic Pharmaceutical Forum	N=5 Denmark, Iceland, Finland, Norway and Sweden	2015	Old & new hospital medicines	• Horizon scanning • Joint procurement • Reimbursement negotiations • HTAs • Information Sharing	Collaborative actions in all activity areas listed
FaAP	N=5 Czech Republic, Hungary, Lithuania, Poland, Slovakia	2017	High-priced medicines	• Horizon scanning • Price negotiations • Information sharing	First joint workshop held in 2019 & assessment of how countries can work together
VALETTA Declaration	N=10 Cyprus, Greece, Ireland, Italy, Malta, Portugal, Romania, Spain, Slovenia, Croatia	2017	Particular focus on oncology drugs, treatments for autoimmune diseases, orphan drugs, biosimilars, and products with a potentially substantial budget impact	• Horizon scanning • Joint HTAs • Joint pricing & reimbursement negotiations • Exchange of strategic information	The Valletta declaration is at an early stage and no product has yet passed through the joint clinical, economic or price negotiation processes
FINOSE	N=3 Estonia, Latvia, Lithuania	2018	New technologies	• Joint clinical and economic assessments	Joint assessment of 3 technologies

Abbreviations: HTA, Health Technology Assessment.

In theory, joint HTA activities can support the decision needs of participants and their health systems along the full technology lifecycle (Figure 1), benefiting from cross-country learning and improving transparency through information sharing. In addition, HTA collaborations will allow country-level regulators to share workloads and reduce duplicative efforts, thus enabling medicines to come to market at a faster pace.

Figure 1. Proposed position of joint HTA activities along the lifecycle of a health technology indication



Observed challenges for EU-wide HTA/pricing collaborations

Whilst the implementation of EU-wide joint HTAs may provide additional benefits over the multitude of existing national assessments, several challenges are anticipated for both collaboration members and pharmaceutical companies (4,5):

- Significant cross-country differences in healthcare systems, mentality and willingness to pay
- Need for streamlining the definitions of clinical value, quality of evidence and requirements for real-world evidence
- Significant variability in treatment pathways and current standard of care, therefore relevant comparators, across markets
- Cross-border joint price negotiations may impact net price confidentiality
- Pharmaceuticals currently constitute the primary focus of joint HTAs; guidance for medical devices remains scarce
- HTA frameworks and legal aspects at national level may require amendment to allow adoption of joint clinical assessment opinions and subsequent pricing negotiations

Conclusions and implications for the biopharma industry

It is too early to be able to confidently assess the impact of EU-wide HTA and pricing collaborations. Positive results from existing joint HTA initiatives, however, suggest a willingness from both payers and pharmaceutical companies to engage in the process. Despite the potential benefits that such collaborations may present, there is still some uncertainty as to how these will translate into patient access in the individual countries while avoiding the unnecessary duplication of work. Whilst central assessment of the clinical efficacy of new technologies is possible, HTA bodies and national authorities will still want to understand local epidemiology, unmet needs and assess the budget impact. This may in turn add complexity and burden for pharmaceutical companies who may be required to prepare separate submissions to EUnetHTA for joint clinical assessment and, subsequently, to national bodies for economic assessment and pricing negotiations. Closer collaborations between the local/regional affiliates may also be required. An additional question that the biopharma industry will need to consider is how a joint HTA process may impact launch sequencing. Furthermore, navigating pharmaceutical company confidentiality concerns is a consistent challenge, and it is unclear how this will be addressed moving forward.

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ISPOR Europe 2022, 6–9 November 2022, Vienna, Austria

(Stand No. X2-304)

References

1. Fontrier, AM., Visintin, E., and Kanavos, P. 2022. Similarities and Differences in Health Technology Assessment Systems and Implications for Coverage Decisions: Evidence from 32 Countries. PharmacoEconomics Open 6, 315–328.
2. The European Parliament and the Council of the European Union. Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on Health Technology Assessment and amending Directive 2011/24/EU. Official Journal of the European Union L 458/1. 22.12.2021. 2021. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R2282&from=E. Accessed 26 September 2022.
3. EUnetHTA, 2021, EUnetHTA Joint Action 3 - WP1: A Future Model Of HTA Cooperation. Final White Paper.
4. Kanavos, P., Angelis, A., and Drummond, M. 2019. An EU-wide approach to HTA: An irrelevant development or an opportunity not to be missed?. Eur J Health Econ 20, 329–332.
5. WHO. 2020. Cross-country collaborations to improve access to medicines and vaccines in the WHO European Region. Copenhagen: WHO.

Abbreviations

BeNeLuxA-I: Belgium, Netherlands, Luxemburg, Austria, and Ireland collaboration
EU: Europe
EUnetHTA: European Network For Health Technology Assessment
FaAP: Fair and Affordable Pricing Initiative
FINOSE: Finland, Norway and Sweden collaboration
HTA: Health Technology Assessment