

# European voluntary cross-border collaborations in joint HTA and drug pricing/procurement: Recent developments and impact of EU HTA regulation

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## Background and objectives

Over the past decade, several European countries have pooled resources to conduct joint HTA or drug pricing/procurement to ultimately improve access to medicines and secure affordable prices. This research explores recent developments in European voluntary cross-border HTA and drug pricing/procurement initiatives from 2023 onwards, and their readiness for upcoming EU HTA implementation in 2025.

## Methods

A literature review was conducted using publicly available resources—the WHO website, national health authorities' websites, MEDLINE, and grey literature.

## Results

- Among 13 European cross-border initiatives that have been established since 2015, few well-established initiatives have remained particularly active, which include **BeNeLuxA** (established in 2015), **NLF** (established in 2015), and **JNHB** (formerly **FINOSE**, established in 2018) (**Table 1**)
- Other more recently established initiatives are evolving and exploring collaboration between European and non-European countries (**Table 2**)

**Table 1. Active, well-established cross-border collaborations**

Name of collaboration	BeNeLuxA	NLF	JNHB
Countries involved			
Start date	2015	2015	2018
Scope			
Joint HTA	✓	✗	✓
Joint negotiations/pricing	✓	✓	✗
Joint procurement/tendering	✗	✓	✗
Horizon scanning	✓	✗	✓
Information sharing	✓	✓	✗
Recent advances	<ul style="list-style-type: none"><li>Despite the initial failure to reach an agreement in 2023, <b>Belgium, Ireland, and the Netherlands successfully completed joint price negotiations for atidarsagene autotemcel in 2024</b> based on joint HTA procedure involving the 3 countries. This success was driven by the availability of new long-term data, which resulted in overall 3 of 5 joint price negotiations ending in an agreement (1-3)</li><li><b>In 2024, BeNeLuxA has conducted a joint HTA for another expensive gene therapy etranacogene dezaparvovec</b>; however, the Netherlands and Belgium opted for individual price negotiations because of organizational differences in financing of the current SoC (1,4,5)</li><li><b>The Czech Republic is also exploring a closer cooperation with BeNeLuxA</b> (6)</li></ul>	<ul style="list-style-type: none"><li>The <b>FINOSE project</b>, originally established in 2018, which was strengthened by <b>Iceland's</b> entry in 2024, has been relaunched as JNHB, a cross-border HTA collaboration including all Nordic countries (7,8)</li><li><b>JNHB</b> now has a dedicated website that provides access to updated assessment guidance and submission documents to improve the transparency of methods and processes (8)</li><li><b>NLF</b>—a collaboration including key Nordic procurement organizations, which was established in 2015—focuses on joint negotiation/pricing, joint procurement/tendering, and information sharing, and now has a dedicated website to share information on its activities (9)</li><li><b>JNHB has entered a collaboration with NLF, allowing a suitable product assessed through JNHB to undergo joint voluntary Nordic price negotiations through the NED working group within NLF</b> (10-12)</li><li>Five joint HTAs have been published in total (<b>atezolizumab, enzalutamide, betibeglogene autotemcel, atidarsagene autotemcel, and vosoritide</b>), whereas 4 assessments are ongoing (<b>ivosidenib, ivosidenib in combination with azacitidine, omaveloxolone, and tofersen</b>) (13). These joint reports are used to support reimbursement decisions at national level, although negotiations and decisions on reimbursement are outside the remit of the JNHB process. National HTA bodies follow JCAs developed by JNHB, whereas the economic assessment can be adjusted in line with national decision-making requirements (14,15)</li><li>The <b>JNHB's</b> work is supported by the <b>Nordic Horizon Scanning initiatives</b>, which identify new drugs and indications that might benefit from joint assessment and negotiation (12)</li><li>Although <b>JNHB</b> assessments can support national or Nordic price negotiations, the collaboration is not intended to produce joint decisions on recommendations or reimbursement. Instead, these reports serve as a basis for national pricing and reimbursement decisions (7)</li><li>The new <b>JNHB</b> collaboration will continue until June 2026, with the potential for extension depending on outcomes and future developments in the EU joint HTA (7)</li></ul>	
Impact of EU JCA	<ul style="list-style-type: none"><li>Most countries involved in these collaborations participated in <b>EUNETHTA21</b> and contributed to the EU HTAR development, acknowledging the role these collaborations may play in supporting its implementation at national level</li><li>These collaborations have strengthened countries' readiness for joint HTA and are discussing the maintenance of joint HTA procedures subsequent to JCA</li><li>The <b>JNHB</b> members stated that the collaboration is well-prepared for JCA implementation because of its active involvement in the development of EU HTAR (11)</li><li>Members of <b>BeNeLuxA</b> expressed concerns regarding tight timelines, the need for early generation of <b>PICO</b> criteria, and potential overlap with current functions of the collaboration. Furthermore, individual member states will need to overcome organizational challenges to successfully implement EU JCA (16,17)</li></ul>		

Key: ✓ Activity within the scope ✗ Activity not in the scope/no information

**Table 2. Other active cross-border collaborations**

Name of collaboration	WHO/Europe NMP	AUS-CAN-NZ-UK
Countries involved	53 countries including the EU member states	
Start date	2023	2023
Aims/priority areas	<ul style="list-style-type: none"><li>The <b>WHO NMP</b>, launched in early 2023, is focusing on improving access to high-cost medicines and addressing market challenges. NMP operates through 4 working groups on transparency, solidarity, sustainability, and novel antimicrobials, with policy recommendations expected by December 2025 (18)</li><li>In October 2023, the <b>Small Countries Initiative within WHO/Europe</b> was established to address specific challenges faced by the region's 12 smallest member states (19)</li><li>The NMP's Working Group 1, focused on transparency, held its first meeting in December 2023 with participation from the <b>Pan American Health Organization</b> (20)</li><li>In July 2024, the <b>NMP's first regional meeting</b> in Copenhagen discussed horizon scanning and pooled procurement, with representatives from patients, payers, and the pharmaceutical industry (18)</li></ul>	<ul style="list-style-type: none"><li><b>AUS-CAN-NZ-UK Collaboration</b> (established in 2023) emphasizes key priority areas, including work-sharing featuring pilot JCA, enhancing the resilience of HTA systems, strengthening collaboration between regulatory and HTA agencies, and facilitating the exchange of information on COVID-19 and advancements in digital health technologies and AI (21,22)</li><li>Unlike the EU HTA collaboration, the AUS-CAN-NZ-UK group prioritizes simpler, lower-risk HTAs to improve efficiency and align with local health systems. This approach focuses on easier issues first, rather than starting with complex topics like oncology, while still respecting national differences (23)</li></ul>

## Discussion

- The European landscape of HTA is at a pivotal moment with the phased implementation of the EU HTAR. During the time that the regulation introduces mandatory JCAs across member states, other HTA domains, such as economic evaluation and pricing, will remain under national jurisdiction
- Regional initiatives like BeNeLuxA and Nordic initiatives may continue to conduct JCAs for products not covered by JCA before 2030 and collaborate on joint economic assessments, pricing negotiations, horizon scanning, and cross-country PICO development
- The integration of these regional initiatives with the broader EU framework, however, presents challenges. There is a concern about potential duplication of efforts and the need for clear guidelines to ensure transparency and consistency in how JCA reports are integrated into national processes
- Beyond Europe, transcontinental collaborations are also gaining traction. The WHO NMP works with its American counterpart on transparency, whereas the AUS-CAN-NZ-UK collaboration focuses on lower-risk joint HTAs between 4 members of the Commonwealth
- As these collaborations evolve, the impact of the EU HTAR on both regional and global HTA efforts, and vice versa, will need to be closely monitored. The ongoing challenge will be to harmonize these various approaches, ensuring they complement rather than complicate the healthcare landscape, ultimately benefiting patients through timely access to innovative therapies
- With the growing interest in voluntary collaboration within the EU, we can expect further developments on cross-border collaborations during upcoming years. The NCAPR group within the EU has evolved from an ad hoc forum to provide continuous voluntary cooperation focusing on challenges related to pricing/reimbursement, payment, and procurement policies with plans to reinforce existing or new cross-country collaborations (24,25)

## Conclusions

- Established cross-border cooperations like JNHB and BeNeLuxA are poised to maintain their work following EU HTAR implementation
- Given the tight timelines and anticipated challenges for national implementation of EU HTA, these collaborations are expected to streamline and accelerate local processes through PICO alignment and/or integration of JCA reports for national decision-making
- Furthermore, the growing interest within the EU on voluntary cooperation for HTA and European Commission's ambitions to reinforce cross-country collaborations supporting pricing and reimbursement policies highlight the evolving landscape of cross-border collaborations

Key

**Abbreviations:** AI, artificial intelligence; AUS, Australia; CAN, Canada; COVID-19, coronavirus disease 2019; EU, European Union; EUNETHTA, European Network for Health Technology Assessment; HTA, health technology assessment; HTAR, health technology assessment regulation; IFA, International Framework Agreement; JCA, joint clinical assessment; JNBH, Joint Nordic HTA-Bodies; NCAPR, National Competent Authorities on Pricing and Reimbursement; NED, new expensive drug; NLF, Nordic Pharmaceutical Forum (*Nordisk Lægemiddelforum*); NMP, Novel Medicines Platform; NZ, New Zealand; PICO, Patient, Intervention, Comparison, Outcome; SoC, standard of care; UK, United Kingdom; WHO, World Health Organization

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