

# Recent advances in voluntary European cross-border collaborations in joint HTA and drug pricing/procurement

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## Background and objective

- Development of high-cost innovative therapies and supply shortages of hospital drugs have led to cross-border collaborations among many European countries to improve access to and secure affordable prices of medicines
- This research aims to explore developments in European cross-border HTA and drug procurement voluntary initiatives, outside the EUnetHTA

## Methods

- A literature review was conducted using publicly available resources—the WHO website, national health authorities' websites, MEDLINE, and grey literature (from January 2020 to October 2023)

## Results

- Among the 11 European cross-border initiatives established since 2012 (Table 1 and Table 2), only a few have remained markedly active in recent years
- Among these initiatives, recent advances in the **BeNeLuxA** and **Nordic region** collaborations are the most commonly discussed initiatives in literature (Table 2)
- Furthermore, new collaborations among the EU and extra-EU countries have emerged (Table 3)

**Table 1. Cross-border initiatives with no developments published since 2020**

Name of collaboration	Countries involved	Start date
Baltic Partnership		2012
Romanian/Bulgarian IFA		2015
Sofia Declaration		2016
Visegrad+ Collaboration		2017
Iberia Partnership		2017
Valletta Declaration		2017
Southern European+		2017
France/Portugal Declaration of Intent		2017

**Table 2. Active, well-established cross-border collaborations**

Name of collaboration	BeNeLuxA-I	NLF	FINOSE Initiative
Countries involved			
Start date	2015	2015	2018
Scope			
Joint HTA	✓	✗	✓
Joint negotiations	✓	✓	✗
Joint procurement/tendering	✗	✓	✗
Horizon scanning	✓	✗	✗
Information sharing	✓	✓	✗
Recent advances	<ul style="list-style-type: none"> <li><b>Five joint price negotiations</b> [for Orkambi<sup>®</sup> (lumacaftor/ivacaftor), Spinraza<sup>®</sup> (nusinersen), Zynteglo<sup>®</sup> (betibeglogene autotemcel), Zolgensma<sup>®</sup> (onasemnogene abeparvovec-xioi), and Libmeldy<sup>®</sup> (atidisagene autotemcel)] have been conducted so far, <b>but only 2 of them</b> (Spinraza<sup>®</sup> and Zolgensma<sup>®</sup>) have <b>ended in joint agreements</b> (1,2)</li> <li><b>Only Belgium and Netherlands were involved in all joint price negotiations</b>, whereas Ireland (joined in 2018) participated in joint processes for Zolgensma<sup>®</sup> and Libmeldy<sup>®</sup>. <b>Other members (Luxembourg and Austria) were not directly involved in negotiations because of differences in reimbursement systems</b>; however, Austria served as external reviewer in the Belgian procedure for some drugs (1)</li> <li>Members of BeNeLuxA-I have identified 4 medicines in the pipeline that they would like to jointly evaluate in the future (1)</li> </ul>	<ul style="list-style-type: none"> <li><b>The agreement between Denmark, Norway, and Iceland has resulted in 2 successful joint tenders for certain hospital medicines</b> (3,4)</li> <li><b>Two joint negotiations</b> have been completed for new gene therapies (Zynteglo<sup>®</sup> and Libmeldy<sup>®</sup>) (3,5)</li> <li>In 2023, the procurement organisations in Iceland, Norway, Sweden, and Denmark agreed on <b>common guidelines and criteria for joint price negotiations for new medicines</b> (5). Furthermore, <b>Denmark, Sweden, and Norway have entered into a collaboration for ATMPs, which will be open for Finland and Iceland to join</b> (3)</li> <li>Negotiations were based on <b>joint HTAs from FINOSE</b> (3,5)</li> </ul>	<ul style="list-style-type: none"> <li>In 2023, the collaboration was strengthened by the entry of <b>Danish Medicines Council</b> and prolonged for 3 additional years (6)</li> <li><b>Four joint HTAs have been published</b> (clinical and applicable parts of economic assessment) for 2 oncology products [Tecentriq<sup>®</sup> (atezolizumab), Xtandi<sup>®</sup> (enzalutamide)] and 2 gene therapies (Libmeldy<sup>®</sup>, Zynteglo<sup>®</sup>) (7)</li> <li>The goal is to <b>reduce the assessment time to only 90 days</b>; however, the first 3 pilot assessments have taken longer, similar to the normal national assessments</li> <li><b>FINOSE joint HTA advice was followed by individual HTA bodies in terms of clinical assessment</b>; however, the economic assessment could be adjusted in line with national decision-making requirements (8)</li> </ul>

The BeNeLuxA and NLF decided to join forces to tackle challenges in access to new, high-cost therapies. In the joint statement from 2021, the 2 collaborations agreed to work together on issues related to cost-effectiveness assessment and limited availability of robust clinical data to support these assessments (9)

Key:  
 Activity within the scope  
 Activity not in the scope/no information  
 Cooperation between cross-border collaborations

**Table 3. New cross-border collaborations established since 2020**

Name of collaboration	WHO/Europe Access to Novel Medicines Platform	Spain-Cyprus Memorandum of Understanding	Canada/European countries collaboration	AUS-CAN-UK + New Zealand	UK-Taiwan collaboration agreement
Countries involved	53 countries				
Start date	2020	2021	2022	2023	2023
Aims/priority areas	The multistakeholder platform built on the Oslo Medicines Initiative aims to provide <i>neutral</i> environment for allowing different stakeholders (pharmaceutical industries, governments, and patients) to exchange ideas on how to improve access to new and expensive medicines (10-12)	The priorities of the memorandum of understanding (13) are focused on collaboration in the following areas: <ul style="list-style-type: none"> <li>Organ transplantation</li> <li>Tackling antimicrobial resistance</li> <li>Access to innovative medicines</li> </ul>	Future collaboration with the focus on challenges related to negotiating for new, high-priced medicines and sharing of experiences between the organisations (14,15)	Priority areas of this collaboration are work-sharing including <b>plans for pilot JCA</b> , future-proofing of HTA systems, improvement of cooperation between regulatory and HTA agencies, and sharing of information about COVID-19 and developments in digital health technologies and AI (16,17)	Focus on experience sharing between countries, such as the UK's experience in HTA and financial operations of innovative medicines and cancer drug funds, and Taiwan's advancements in big data management and the utilisation of AI (18)

Key: New EU collaborations      Transcontinental collaborations

## Discussion

In coming years, a mandatory EU JCA is to be implemented, although the EU HTA regulation leaves the other domains of HTA (including economic analysis) to national bodies and voluntary collaborations. It is expected that European cross-border collaborations will remain more focused on joint economic evaluation and drug pricing/procurement than on joint clinical assessments. The FINOSE collaboration members expect to continue their work beyond 2025 focusing on products not covered by EU JCA and joint development of health economic evaluations (6). Additionally, the BeNeLuxA collaboration is expected to continue conducting joint economic assessments, joint price negotiations, and horizon scanning.

At this moment, it may be too early to estimate the impact of EU JCA on cross-border collaborations and manufacturers. So far, voluntary collaborations have shown that joint assessment of medicines may limit workload of HTA bodies and companies, without additional assessment time. However, initiatives such as the BeNeLuxA or FINOSE include smaller countries that share similarities in their approach to HTA. **It remains to be demonstrated how JCA involving all the EU countries, including larger markets so far not interested in collaboration (like Germany or France), will work in practice.**

## Conclusions

- Some established European cross-border alliances, such as the BeNeLuxA and Nordic collaborations, continue to be active and to seek new partners for pooling resources and bargaining power. However, since 2020, no further developments have been publicly available for other launched initiatives
- With the implementation of the new EU HTA regulation, it is expected that the existing European collaborations will remain more focused on joint economic evaluation and drug pricing/procurement than on joint clinical HTA
- Furthermore, new transcontinental alliances are being established, with plans for joint clinical assessment between the United Kingdom, Australia, and Canada
- It would be interesting to further assess how these collaborations evolve and affect each other at both EU and extra-EU levels

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- Key:  
 Latvia   Norway   Sweden   Croatia   Hungary   Romania   Greece   Italy   The United Kingdom  
 Lithuania   Iceland   Denmark   Malta   Austria   Serbia   Australia   Luxembourg   New Zealand  
 Estonia   Finland   Bulgaria   Slovenia   Macedonia   Slovakia   Poland   Taiwan   The Czech Republic  
 Portugal   Spain   Canada   Cyprus   Belgium   Ireland   The Netherlands

Abbreviations: AI, artificial intelligence; ATMP, advanced therapy medicinal product; AUS, Australia; CAN, Canada; COVID-19, coronavirus disease 2019; EU, European Union; EUnetHTA, European Network for Health Technology Assessment; HTA, health technology assessment; IFA, International Framework Agreement; JCA, joint clinical assessment; NLF, Nordic Pharmaceutical Forum (*Nordisk Lægemiddelforum*); UK, United Kingdom; WHO, World Health Organization

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