



Recent Advances In The European Cross-border Collaboration In Joint Drug Procurement Landscape

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OBJECTIVES

- Growing costs of innovative medicines have triggered many European countries to start collaboration to improve patient access to high-cost medicines. In response to that, EFPIA recently published its position to support development of such initiatives.¹³
- The aim of this research was to update the landscape of cross-border drug procurement initiatives that recently emerged in Europe.

METHODS

- A literature review was conducted using publicly available resources such as the European Commission website, WHO website, European Federation of Pharmaceuticals Industries and Associations, national health authorities' websites, Medline® database, and grey literature.

RESULTS

- Thirteen regional initiatives (Table 1) in pharma procurement were established since 2012 including about 28 European countries with main scope of activity including information sharing, horizon scanning, and joint HTA/price negotiations of innovative medicines with few collaborations focused on biosimilars/generics (Iberia Partnership) and advanced vaccines (Baltic Partnership). Among these initiatives, recent advances in Valletta, BeNeLuxA-I and Nordic region collaborations were the most commonly discussed in literature while no updated information was identified for others.

Table 1. Cross-border collaborations	Start date
Baltic Partnership	2012
BeNeLuxA-I	2015
Nordic Collaboration	2015
Romanian/Bulgarian IFA	2015
Nordic Pharmaceuticals Forum (NLF)	2015
Sofia Declaration	2016
Visegrad+ Collaboration	2017
Iberia partnership	2017
Valletta Declaration	2017
Southern European+	2017
France/Portugal declaration of intent	2017
FINOSE Initiative	2018
Norwegian/ Danish initiative	2018

☐ Available information on collaboration activity

Valletta Declaration

- Valletta collaboration announced prioritisation criteria for joint clinical/economic evaluation and price negotiations focusing mostly on oncology drugs, autoimmune diseases, orphan drugs, biosimilars and products with a potentially substantial budget impact.^{8,9}
- No product has yet been jointly evaluated or passed through price negotiation process. However, **six products** have been already selected for work, including **CAR-T cell therapy** for advanced cancer.⁸
- In 2019, WHO accepted **WHA72 resolution sponsored by the Italy**, one of Valletta group members, which aims to promote greater price transparency.
 - Current efforts of the group seems to focus on implementation of resolution and increasing of **price transparency**, beginning from confidential price sharing between member states.^{8,10}
- The Valletta Technical Committee is working on the proposal to jointly target problem of **antimicrobial resistance**. Group wants to engage with farmaceutical industry to support development of new antibiotics and increase affordability of treatment.^{11,12}

CONCLUSIONS

- Several cross-collaboration initiatives on joint drug procurement have emerged over last 7 years in Europe. A successful results of BeNeLuxA-I negotiations of nusinersen seemed a breaking point for other European countries to undertake similar initiatives.
- Nordic region is the most rapidly evolving in the European landscape of cross-border collaborations on joint drug procurement landscape.
- The evolution process of collaborations has apparently two dimensions, one has a geographical aspect reflecting a historical experience of collaboration between countries within a region, while the second indicates at progression of other activities from the collaborations scope beyond joint HTA/pricing, includind horizon scanning at transcontinental level, and promotion of price transparency.
- The evolution of cross-border collaborations on drug procurement so far omits high-income countries like the UK, Germany or France which has an observer status at Valletta's meetings.
- Most of pilot projects have been focused on costly orphan drugs targeting vulnerable population of patients with significant unmet needs or oncology drugs. Majority of cross-border collaborations are in infancy and still need to overcome significant hurdles to become truly effective.

RESULTS (C.D.)

- **BeNeLuxA-I** is the most promising cross-border collaboration in Europe and, to date, the only one with **confirmed successful joint HTA** price negotiations of nusinersen in SMA in 2018 (Box 1).

Box 1. BeNeLuxa-I¹

- Following **first success**, BeNeLuxA-I is currently involved in price and reimbursement negotiations of **three other medicines** meeting the selection criteria (high unmet need product not yet being a subject of reimbursement in any member state). However, as of Sept 2019, names of these drugs are unknown until the end of the negotiations.
- Moreover, BeNeLuxA-I seems to strengthen cooperation beyond joint HTA/pricing field by fostering the development of **International Horizon Scanning Initiative (IHSI)**, which is open to any interested country. **Sweden and Canada** have already been announced to join the initiative. It is estimated that **10 countries** will join the initiative and official launch is planned at the beginning of 2020.^{1,2,3}
- There has been a growth in collaboration between Nordic countries with two main initiatives emerging on the horizon last years (Box 2).

Box. 2 Nordic initiatives

Norwegian-Danish Initiative ⁴	• Established in Sept 2018, Norwegian-Danish procurement initiative aims to negotiate lower prices for high cost products and also to secure access to low-cost, generic medicines. • The initiative was set up despite previous failure of price negotiations of nusinersen in SMA led by the two countries with pharma industry earlier in 2018. • Expanded in 2019 following an inclusion of Iceland.
FINOSE collaboration	• FINOSE project jointly led by Finland, Sweden and Norway since March 2018 aims to improve HTA process by information sharing and conducting joint assessments; is it pilot phase until summer 2020.⁵ • Notably, member states expressed their will to proceed with collaboration in parallel to EUnetHTA joint action 3 (JA3) to avoid unnecessary work duplication and competition between initiatives.⁵ • Selection process for pilot FINOSE assessments considers products that have relevant comparators in each country member of the initiative, excluding products already assessed within JA3.⁵ • To date, there have been two reports from joint HTA published, one for Xtandi® (enzalutamide) - 1st line therapy of high-risk non-metastatic CRPC⁶, and second for Tecentriq® (atezolizumab) - 1st line therapy of metastatic NSCLC⁷, both concerning oncology products with final outcome driven mostly by economic uncertainty.

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