How the EU JCA could interface with Regional Pricing Alliances (BeNeLuxA, JNHB, Valletta Group) and EU-Level Procurement under the CMA?

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INTRODUCTION

- Regional alliances such as FINOSE/JNHB, BeNeLuxA, and the Valletta group collaborate on joint HTA and pricing to increase negotiating power, reduce duplication of assessment work, harmonise methods, and accelerate patient access[1-3]
- EU Joint Clinical Assessment (JCA) will provide a common evidence base, which alliances may use to streamline processes by avoiding duplication of assessments[4]

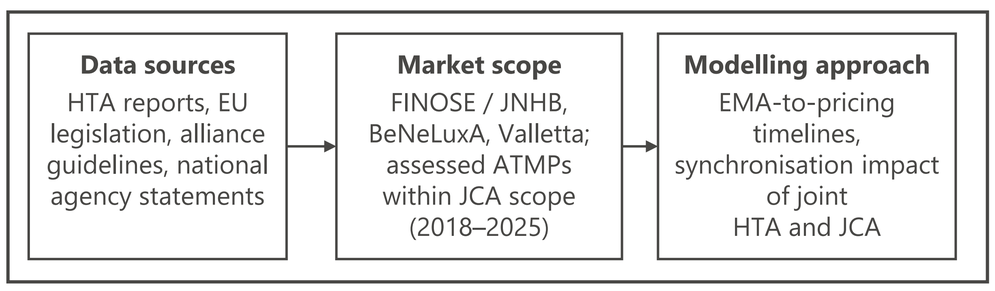
OBJECTIVES

- To analyse how the mandatory JCA could interface with regional joint pricing alliances, such as the BeneluxA Initiative for Health Technology Assessment (BeNeLuxA), the Joint Nordic Health Technology Assessment Bodies (JNHB), and the Valletta Declaration Group
- To assess the downstream consequences for European market-access pathways, including potential escalation to EU-level procurement under the draft Critical Medicines Act (CMA)

METHODS

- HTA reports, EU legislative texts, alliance process guidelines, and recent statements from national HTA agencies were reviewed to characterise cross-country HTA processes and their intended integration with the EU Joint Clinical Assessment (JCA)
- Across the Nordic countries (FINOSE/JNHB), BeNeLuxA, and the Valletta group, advanced therapy medicinal products (ATMPs) that would have fallen within the scope of the EU Joint Clinical Assessment (JCA) regulation were assessed to determine the current frequency of cross-country joint HTA between 2018 and 2025
- Timelines from EMA approval to the conclusion of pricing negotiations were modelled for ATMPs with completed joint assessments and negotiations to illustrate the potential impact of synchronising joint HTA submissions with JCA publication

Figure 1. Study methodology overview



RESULTS

- Of the 18 ATMPs authorised by the EMA between 2018-2025 that would have fallen within the scope of the JCA (**Figure 2**):

FINOSE / JNHB evaluated 3 therapies (17%) for joint HTA and completed full assessments for 2 (11%)[5]	**BeNeLuxA** evaluated 4 therapies (22%) for joint HTA and completed full assessments for 3 (11%)[6]	No product has yet passed through the **Valletta** joint clinical, economic or price negotiation processes

- Observed timelines from EMA approval to completion of joint price negotiations ranged from approximately 508 to 853 days across the modelled ATMPs (**Table 1**)
  - The interval from EMA approval to joint HTA completion ranged from 368 to 672 days, followed by pricing negotiation phases of 140 to 333 days (**Figure 3**)
- In the modelled JCA scenarios, where companies were assumed to submit dossiers following JCA endorsement, timelines from EMA approval to completion of joint price negotiations were shortened by between 254 to 558 days across the modelled ATMP (**Table 1**, **Figure 3**)

Figure 2. Number of ATMPs authorised by EMA (2018–2025) within JCA scope and the number undergoing joint appraisal and negotiation[5-8]

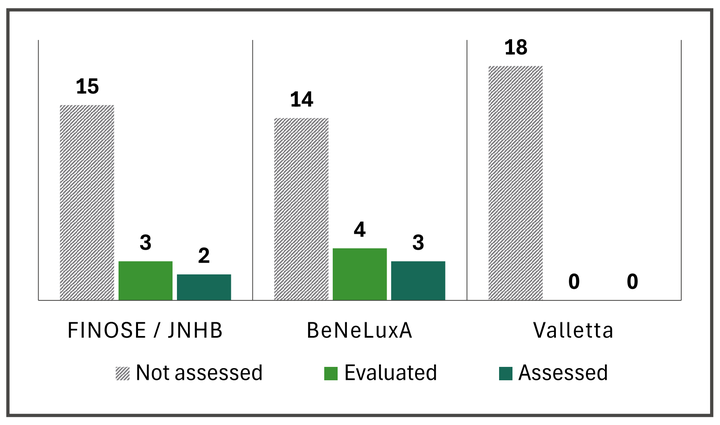
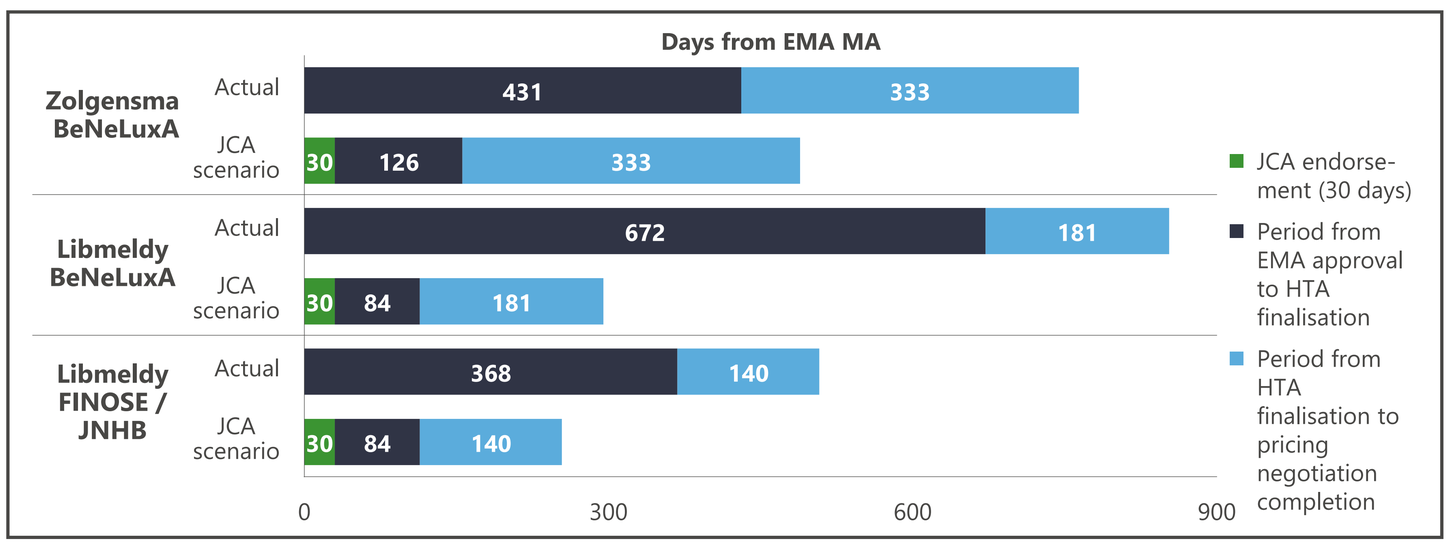


Table 1. Total Timelines from EMA approval to completion of joint HTA and price negotiations, with modelled JCA scenarios[5-6]

Alliance	FINOSE / JNHB	BeNeLuxA	BeNeLuxA
Therapy	Libmeldy	Libmeldy	Zolgensma
Observed total days (months)	764 (25)	853 (28)	508 (17)
JCA scenario days (months)	489 (16)	295 (10)	254 (8)

Figure 3. Timelines from EMA approval to completion of joint HTA and price negotiations, with modelled JCA scenarios[5-6]



CONCLUSIONS

1. Joint HTAs for ATMPs have been infrequently utilised, with our analysis showing fewer than 15% of products within scope completing both a joint assessment and negotiation across alliances
2. Regional alliances such as FINOSE/JNHB and Beneluxa have already expressed their intention to expand the number of joint assessments, and we speculate that JCA could provide the impetus for this expansion, by delivering a single, authoritative clinical evidence base that alliances can directly reuse[9]
3. For companies that synchronise their submissions to joint alliances with JCA endorsement, our results suggest that the time from EMA marketing authorisation to the conclusion of pricing negotiations could be shortened
4. However, companies will have to balance the potential for a shortened access duration with the overall impact on access and negotiation strategies
5. Ultimately, if ATMPS fail to gain access through national or alliance pathways, a completed JCA provides the gateway to joint procurement under the CMA if ratified, offering an alternative route to secure access[10]

References: [1]JNHB. Memorandum of Understanding 2024 [Available from: https://jnhtabodies.org/media/2k2flrxu/memorandum-of-understanding-2024.pdf; [2]Beneluxa. The Beneluxa Initiative on Pharmaceutical Policy 2018 [Available from: https://beneluxa.org/sites/beneluxa.org/files/2018-10/180622%20Terms%20of%20Reference%20Beneluxa%20Initiative_0.pdf; [3]The Valletta Declaration. Good practice in medicines procurement and negotiation to improve access to effective treatment and support sustainability of healthcare systems 2021 [Available from: https://www.ipaac.eu/res/file/roadmap/id005.pdf; [4]European Commission. Joint Clinical Assessments 2022 [Available from: https://health.ec.europa.eu/health-technology-assessment/implementation-regulation-health-technology-assessment/joint-clinical-assessments_en; [5]JNHB. Joint assessments 2025 [Available from: https://jnhtabodies.org/assessments/; [6]Beneluxa. Archive 2025 [Available from: https://beneluxa.org/archive; [7]ESGCT. The 25 authorised ATMPS in the EU 2023 [Available from: https://www.eurogct.org/sites/default/files/attachments/resources/3_poster-isct-2023_ma-of-atmps_table-25-authorised-atmps-in-eu.pdf; [8]European Commission. List of ongoing joint clinical assessments 2025 [Available from: https://health.ec.europa.eu/latest-updates/updated-list-ongoing-joint-clinical-assessments-2025-09-02_en.]; [9]JNHB. FINOSE becomes Joint Nordic HTA-Bodies 2024 [Available from: https://jnhtabodies.org/media/jfgloqc4/jnhb-launch-3-june-2024.pdf; [10]European Comission. Summarising evidence supporting the legislative proposal laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicines of common interest and amending Regulation (EU) 2024/795. 2025.

Abbreviations: ATMP: Advanced therapy medicinal product; BeNeLuxA: Belgium, Netherlands, Luxembourg, Austria; CMA: Critical Medicines Act; EMA: European Medicines Agency; EU: European Union; HTA: Health technology assessment; JCA: Joint Clinical Assessment; JNHB: Joint Nordic Health Technology Assessment Bodies

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