Fragmentation in Access Pathways: A Review of HTA and Decision-Making Processes for Medicines in Finland

HPR98

S. Torvinen,[1] R. Viitanen,[1] M. Mähönen,[1] T. Ylisaukko-oja[1]

[1]MedEngine Oy, Helsinki, Finland

Introduction

- Under the Health Insurance Act, the Pharmaceuticals Pricing Board (PPB) must issue a decision on an application concerning the price and reimbursement status of a medicine within 180 days, and on a price increase application within 90 days.[1]
  - When negotiations on conditional reimbursement begin, the processing of the application is suspended for the duration of these negotiations.[2]
- There are no legally defined maximum processing times for the evaluation of hospital medicines. The Finnish Medicines Agency (Fimea) has estimated that its evaluation process takes approximately 3–4 months from the time the Committee for Medicinal Products for Human Use (CHMP) opinion becomes available.[3]
- The subsequent recommendation process by the Council for Choices in Health Care in Finland (COHERE), which starts after Fimea's assessment, takes about 4–5 months.[4]

Objectives

1. **To evaluate the structure and functioning of Finland's multi-channel health technology assessment (HTA) and decision-making system for outpatient and hospital medicines**
2. **To identify differences within this system in terms of evaluation timelines and implementation outcomes**

Methods

- This analysis included medicinal products that were granted marketing authorization between 2020 and 2022.[3]
  - Vaccines and COVID-19 medicines were excluded from the analysis.
- The study material consisted of all new, first-to-market products (n=183) that received a recommendation from the CHMP between 1.1.2020–31.12.2022.
- National HTA decisions regarding approval or rejection, access recommendations, and the eventual adoption of the products into use were systematically reviewed.
- The study compared the processing times of different HTA authorities.

Results

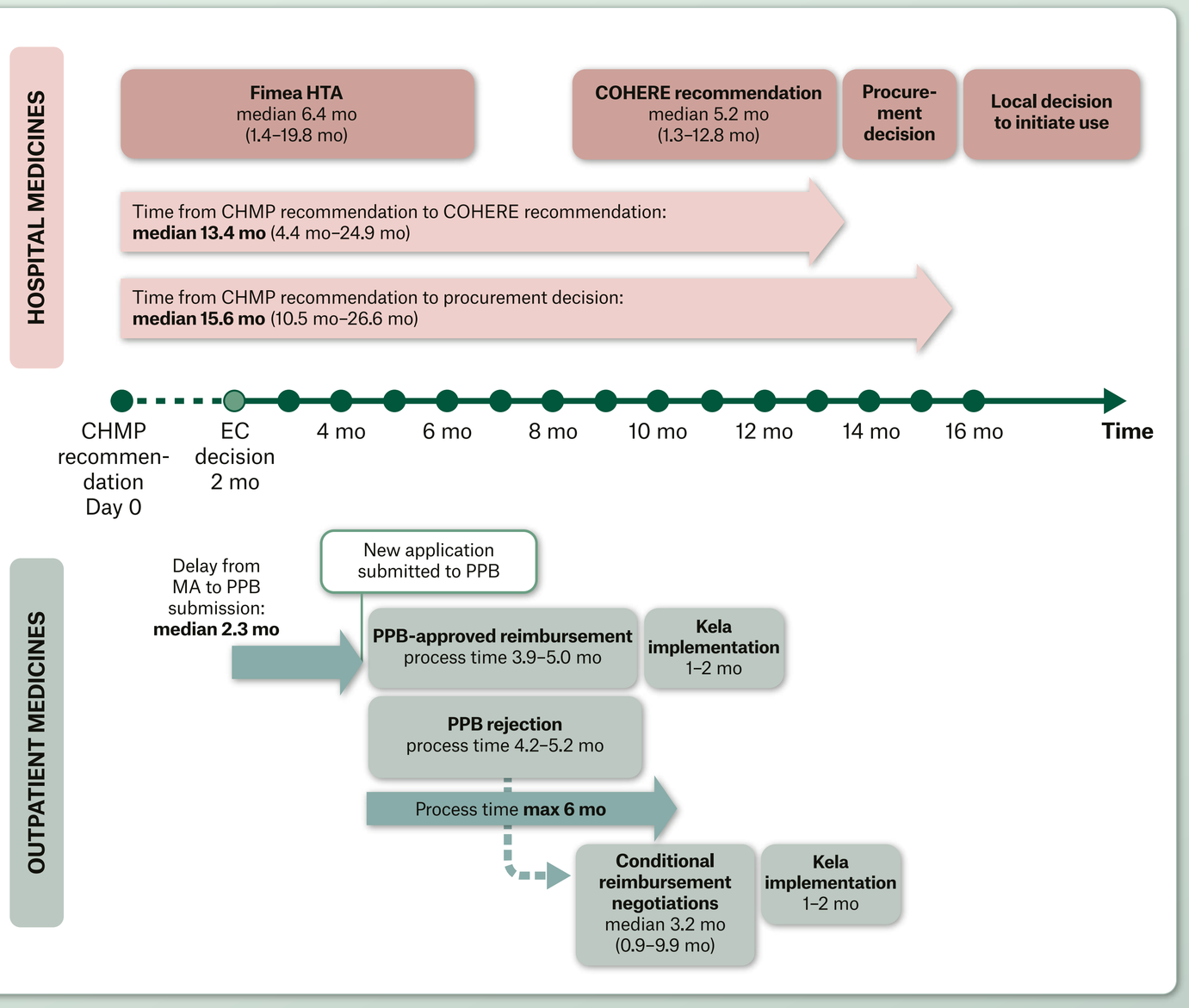

Figure 1. Timelines of HTA evaluation processes. CHMP, Committee for Medicinal Products for Human Use; COHERE, Council fo Choices in Health Care; EC, European Commission; HTA, health technology assessment; Kela, The Social Insurance Institution of Finland; MA, marketing authorization; mo, month; PPB, Pharmaceuticals Pricing Board.

- According to the PPB website, between 2020 and 2022, the processing time for basic reimbursement applications for medicines with new active substances was 3.9–5.0 months for products approved for inclusion in the reimbursement system and 4.2–5.2 months for those that were rejected.[2]
- For conditionally reimbursed medicines, the median duration of conditional reimbursement negotiations was 3.2 months (range: 0.9–9.9 months).[2]
- Reimbursement does not take effect immediately after the PBB decision. Instead, it is followed by an implementation phase by the Social Insurance Institution of Finland (Kela). Therefore, reimbursement typically enters into force within 1–2 months after the decision.[5]
- After the CHMP recommendation, the average duration of Fimea's evaluation was 6.4 months (range 1.4–19.8 months).
- The duration of COHERE's recommendation process was measured from the date when Fimea's assessment report became publicly available. The median duration of COHERE's evaluation process was 5.2 months (range: 1.3–12.8 months).
  - The median time from the CHMP recommendation to the completion of COHERE's recommendation was 13.4 months (range: 4.4–24.9 months).
- The procurement decision following COHERE's recommendation extended the timeline by several months, resulting in a median total duration of 15.6 months (range: 10.5–26.6 months) from the CHMP recommendation to the implementation date specified in the procurement decision.

Conclusions

- These findings highlight significant disparities in HTA processes between outpatient and hospital medicines in Finland.
- The fragmented framework contributes to variation in access timelines and implementation.
- Improved alignment, transparency, and binding guidance could improve consistency and equity in patient access to new, effective treatments.

Contact information:

Saku Torvinen, Director Market Access
saku.torvinen@medengine.fi

Acknowledgments: The authors would like to thank all the interviewed stakeholders and the steering group members of the initial study.

Disclosures: The authors declare no conflicts of interest.

References: 1. Health Insurance Act 1224/2004. Finlex Database. Available at: https://www.finlex.fi/en/laki/ajantasa/2004/20041224; 2. Pharmaceuticals Pricing Board (Hila), 2025. Official website. Available at: https://www.hila.fi; 3. Finnish Medicines Agency (Fimea), 2025. Official website. Available at: https://www.fimea.fi; 4. Council for Choices in Health Care in Finland (COHERE / Palko), 2024. Palko Handbook. Available at: https://palveluvalikoima.fi/periaatteet; 5. Social Insurance Institution of Finland (Kela), 2025. What happens after a PPB (Hila) decision? Available at: https://www.kela.fi/tietoa-kelasta-laakeyritykset-laake-sai-korvattavuuden

MedENGINE