Mapping Access Pathways for New Medicines in Finland: A Real-World Review of HTA and Reimbursement Decisions

HPR136

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Introduction

- At present, available evaluation resources are not sufficient to assess all new hospital medicines, let alone their new indications.
- Retail reimbursement for medicines is initiated by an application from the Marketing Authorisation Holder (MAH) to the Pharmaceuticals Pricing Board (PPB), whereas access to hospital medicines — and their evaluation — can be requested by the MAH or initiated by the Finnish Medicines Agency (Fimea) or other stakeholders.

Objectives

1. **To analyze the evaluation and access outcomes of new medicinal products in Finland across both the outpatient and hospital channels**
2. **To quantify the role of national health technology assessment (HTA) bodies and reimbursement agencies in determining medicine availability in Finland**

Methods

- This retrospective mapping study included 183 new medicines authorized in Finland between 2020 and 2022.[1]
  - Vaccines and Covid-19 medicines (n=23) were excluded from the dataset.
- Medicines were categorized into outpatient (n=94) and hospital (n=66) categories based on the route of administration and the assessing authority.
- Data were extracted on evaluation activity across key institutions, including Fimea, the Council for Choices in Health Care in Finland (COHERE) and the PPB, reimbursement outcomes, and final access or procurement decisions.

Results

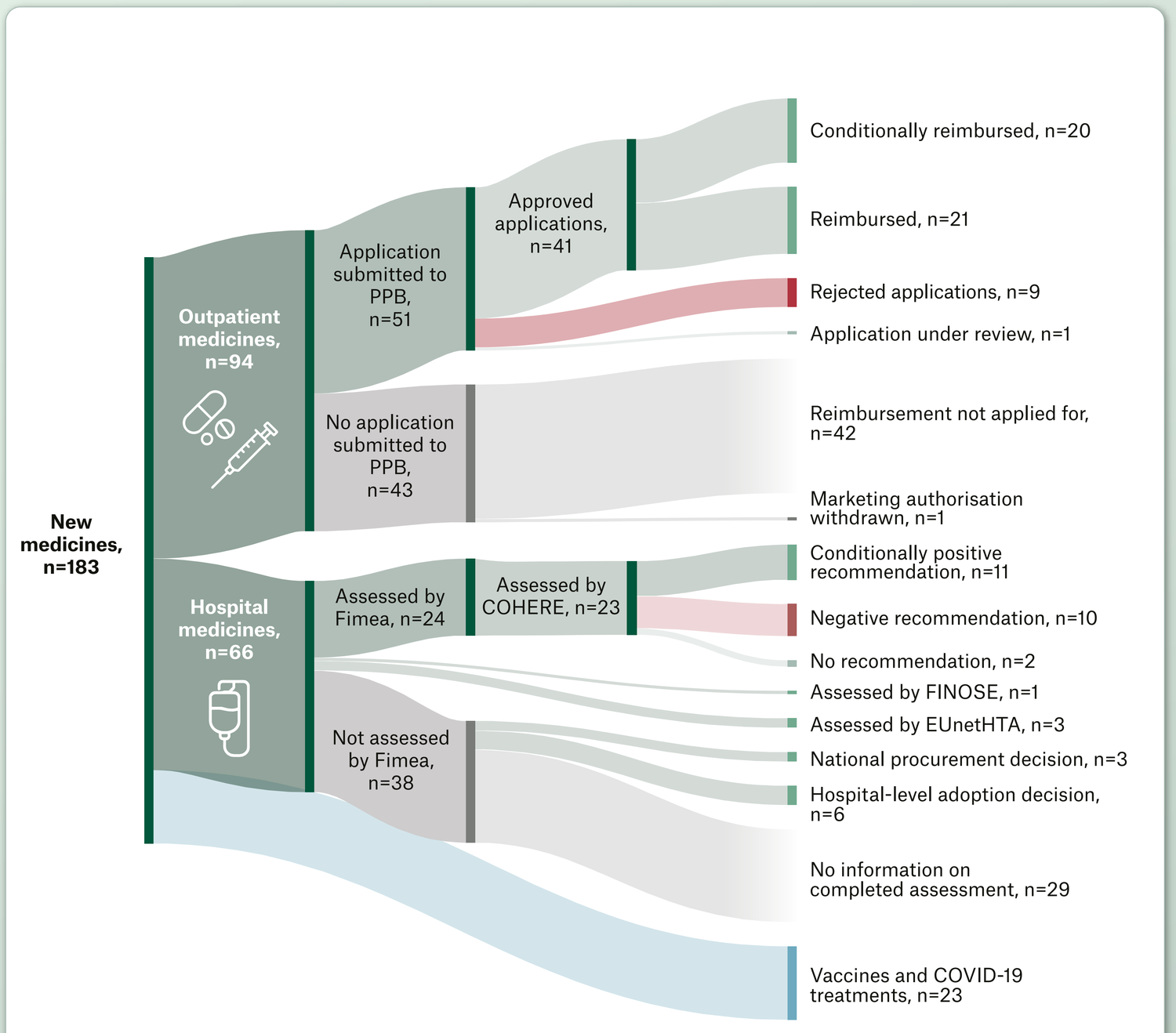

Figure 1. HTA evaluations and corresponding decisions in Finland in 2020–2022. COHERE, Council fo Choices in Health Care; EUnetHTA, European Network for Health Technology Assessment; Fimea, Finnish Medicines Agency; FINOSE, re-launched as JNHB (Joint Nordic HTA-Bodies); HTA, health technology assessment; PPB, Pharmaceuticals Pricing Board.

Outpatient medicines

- Of the outpatient medicines (n=94), 51 (54%) were submitted to the PPB for reimbursement evaluation.[2]
  - Of these, 41 (80%) were approved: 21 outpatient medicines received reimbursement and 20 received conditional reimbursement.[2]
  - Nine applications were rejected, and one was still under review at the time of data extraction. Notably, reimbursement applications had not been submitted for 43 outpatient medicines (46%).[2]

Hospital medicines

- Of the hospital medicines (n=66), 24 were assessed through Fimea's HTA, and 23 of these also underwent COHERE assessment.[1,3]
  - COHERE issued 11 conditional and 10 negative recommendations.[3]
- Access outcomes of hospital medicines varied:
  - 3 medicines received national procurement decisions[4]
  - 6 medicines were evaluated at the hospital level (mini-HTA)[5]
  - 29 medicines had no publicly available assessment data
  - FINOSE assessed 1 medicine and EUnetHTA assessed 3 medicines
- A total of 38 hospital medicines (55%) were not assessed by Fimea.

Conclusions

- The Finnish access system demonstrates fragmentation and variability across both outpatient and hospital channels.
- A large proportion of new medicines remain unevaluated or outside formal reimbursement channels.
- Improved coordination and transparency in HTA evaluations and procurement processes may enhance equitable and timely access.

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