HTA Submission Trends for EMA-Approved Oncology NASs Prior to the EU HTA Regulation (2018–2023)

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HTA190

Introduction

Timely access to medicines in European countries is currently unequal due to some health technology assessment (HTA) agencies receiving earlier submissions than others, company strategy and/or differences in HTA review time length, among other reasons. The EU HTA Regulation, implemented initially for oncology and ATMP products in January 2025, strives to improve timely access to medicines across Europe.

Objective

To baseline the submission trend for oncology medicines in Europe prior to Joint Clinical Assessment (JCA) implementation.

Methods

Regulatory approval dates: extracted EU commission date from EMA reports for oncology new active substances (NASs) approved between 2018 and 2023.
HTA submission dates: extracted from 1st HTA reports or requested directly from the HTA agencies in France, Germany, Ireland, Netherlands, Poland and Sweden.
Top vs non-top companies: pharmaceutical companies with R&D spending >3 billion USD in 2021, or <3 billion USD, respectively.
Facilitated regulatory pathway (FRP): tagging extracted from EMA reports, i.e. accelerated, conditional, and PRIME.
Submission gap: EMA approval date to HTA submission date.
Analysis: median time and variability (25th and 75th percentiles).

Results

- The EMA approved 231 NASs between 2018 and 2023; 72 were oncology NASs (31%; **Figure 1**).
- France, Germany and Ireland showed a submission gap of less than 2 months (**Figure 2**). The remaining 3 countries' median submission gaps exceeded 5 months.
- The variability of the submission gap was analysed, with France and Germany presenting narrower ranges compared to the rest. Wider ranges were observed for the other 4 countries such as the Netherlands, showing the widest range (**Figure 2**).
- The number of recommended NASs in this 6-year period differ across countries potentially due to different company strategies and the scope of the agencies, as some agencies only review outpatient and not inpatient drugs (**Figure 2**).

Fig 1. NASs approved by the EMA between 2018 and 2023

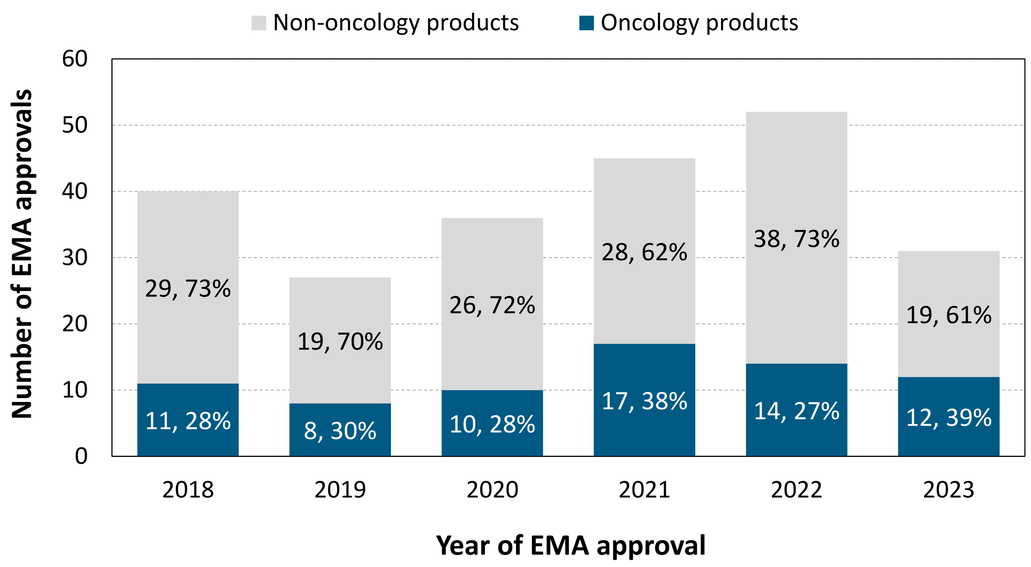
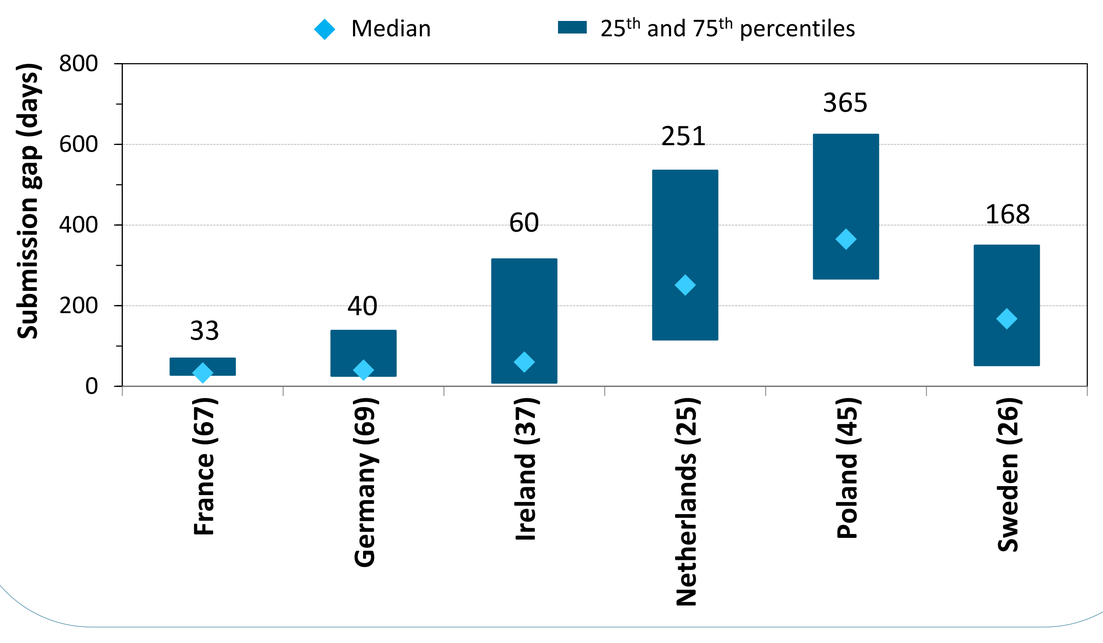


Fig 2. Submission gap of oncology EMA approvals (2018–2023) with a 1st HTA recommendation



- Top companies showed shorter median submission gaps than non-top companies (**Figure 3**). This may be due to top companies tending to have better capacity and resource for local affiliates to prepare the HTA submission report.
- Poland had the longest submission gap overall and across FRPs (**Figure 4**).
- PRIME oncology NASs in Ireland showed the lowest submission gap due to two PRIME NASs submitted in parallel with the regulatory review. Ireland allows HTA submissions after a positive CHMP opinion and before the approval date (**Fig 4**).

Fig 3. Submission gap by company size (oncology EMA approvals 2018–2023 with a 1st HTA recommendation)

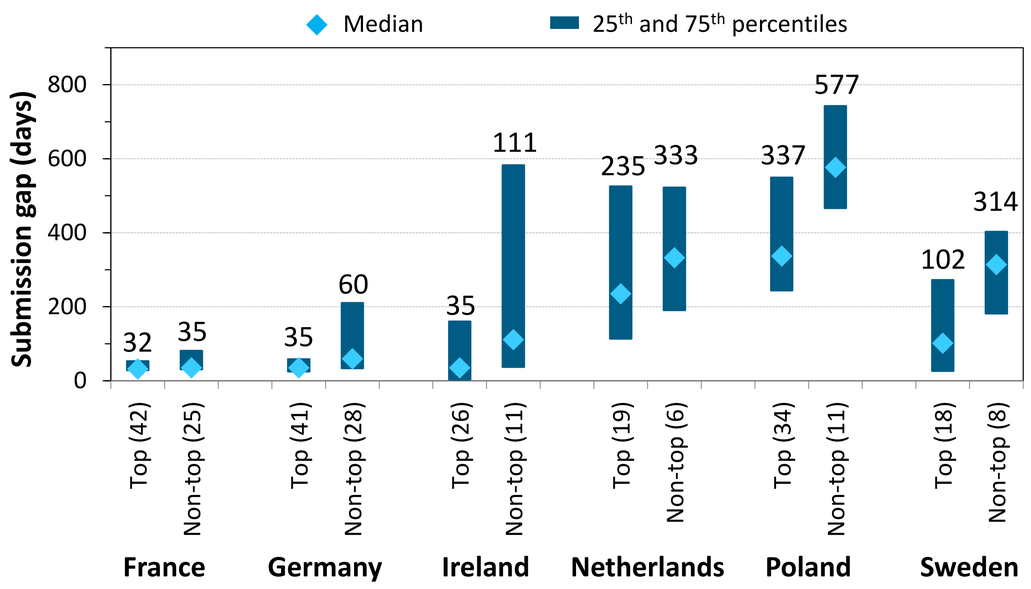
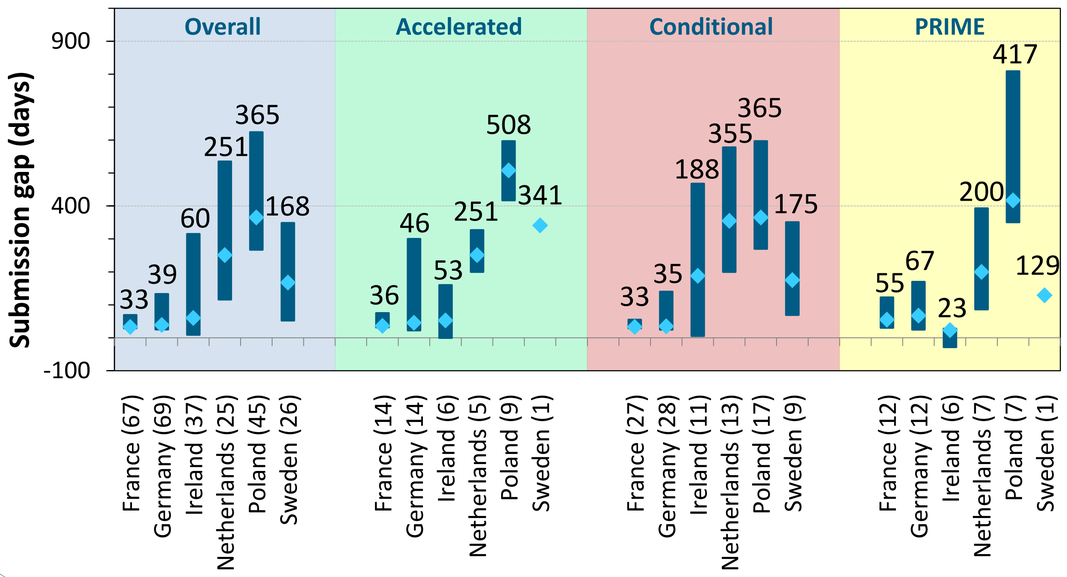


Fig 4. Submission gap by facilitated regulatory pathways (oncology EMA approvals 2018–2023 with a 1st HTA recommendation)



Conclusion

- Approximately a third of EMA approvals between 2018 and 2023 were oncology products.
- The submission gap and variation of this gap is considerably different between countries, with France and Germany demonstrating quicker time to submission.
- The data suggests that factors such as the company size or the FRP the NASs underwent may have an effect on the submission strategy and timeline.
- These results provide a useful baseline to compare to in order to understand whether the HTA Regulation leads to an improvement in submission gaps across Europe.

Centre for Innovation in Regulatory Science (CIRS)

Mission: To identify and apply scientific principles for the purpose of advancing regulatory and HTA policies and processes in developing and facilitating access to pharmaceutical products.

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