HTA222

Life-Years Lost Due to Regulatory and Reimbursement Delays: A Study Of Oncology Drugs Across England, Scotland and France, 2022-24

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BACKGROUND

- Progress in oncology has resulted in the development of innovative therapies that **improve outcomes for patients with cancer**.
- However, **patients face significant delays** accessing new drugs due to complex regulatory and reimbursement processes. For example, the average time from Marketing Authorisation (MA) to reimbursement across the EU was over 1.5 years (586 days) in 2024[1].
- Delays **negatively impact patient outcomes** by postponing access to novel therapies.

OBJECTIVE

Quantify the impact on patients, in terms of **total Life-Years Lost (LYL),** resulting from delays in **regulatory approval and reimbursement** for breast, lung and prostate cancer drugs approved in **England, Scotland and France** between 2022 and 2024.

STUDY DESIGN

Phase 1 – Identification of time and clinical endpoints

- Key timepoints assessed: Proof of efficacy (PoE), defined as the publication date of pivotal trial results; the granting of MA; and the publication of a positive HTA recommendation.
- The key clinical endpoints were overall survival, progression-free survival, disease-free survival and event-free survival.

Phase 2 – Collection of raw data

Data on key temporal and clinical endpoints and estimates of eligible patient populations by country, were extracted from clinical trial publications and HTA reports.

Phase 3 – Standardisation of raw data

Raw data were standardised to annual values to facilitate the calculation of LYL by country.

Phase 4 – Calculation Life-Years Lost

LYL, relative to each drug's statistically significant principal endpoint, were calculated as follows:

*LYL = **Time Delay in Years** x **Clinical Benefit in Years** x **Annual Eligible Patients**.*

CONCLUSION

- Prolonged regulatory and HTA timelines — particularly in **England** and **Scotland** — result in a **loss of life-years** among oncology patients.
- This underscored the urgent need for policymakers to **streamline HTA** procedures and **adopt accelerated pathways** to improve timely access to innovative therapies.

RESULTS

Descriptive statistics:

- A total of 106 oncology drugs indicated for breast, lung, and prostate cancer were assessed in England, Scotland, and France between 2022 and 2024; 78 were excluded based on predefined criteria.
- 28 drug-indication-country observations were included in our analysis (England: 7; Scotland: 10; France: 11)

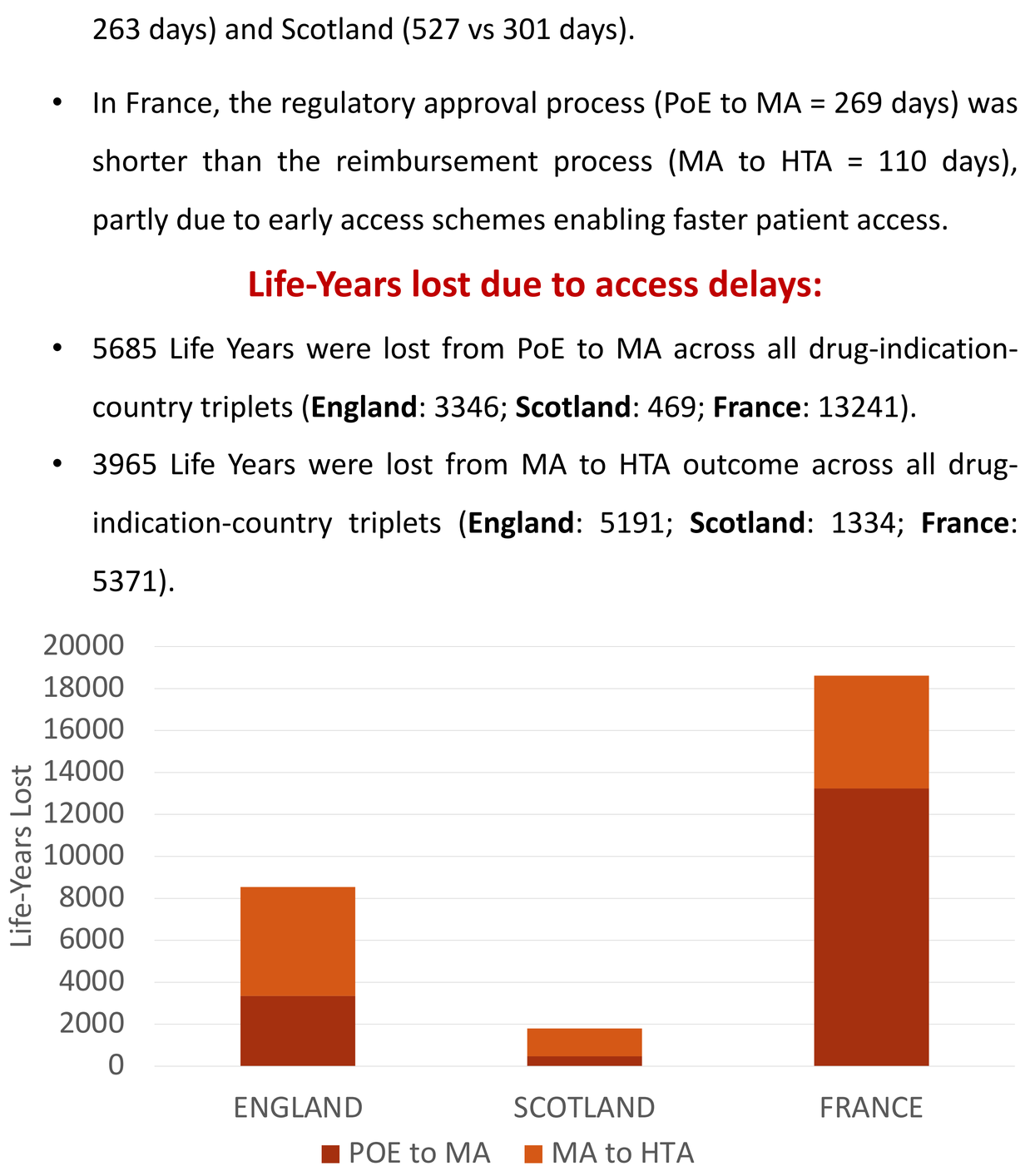
Average time-to-access across the sample:

	PoE to MA (days)	MA to HTA (days)	TOTAL (days)
ENGLAND	263	594	858
SCOTLAND	301	527	828
FRANCE	269	110	380
SAMPLE AVERAGE	278	411	689

- The table shows the average time-to-MA and time-to-HTA by country and across the 28 drug-indication-country triplets. Notably, oncology patients in England and Scotland faced longer delays from PoE to HTA outcome than those in France.
- HTA approval took longer than regulatory approval in England (594 vs 263 days) and Scotland (527 vs 301 days).
- In France, the regulatory approval process (PoE to MA = 269 days) was shorter than the reimbursement process (MA to HTA = 110 days), partly due to early access schemes enabling faster patient access.

Life-Years lost due to access delays:

- 5685 Life Years were lost from PoE to MA across all drug-indication-country triplets (**England**: 3346; **Scotland**: 469; **France**: 13241).
- 3965 Life Years were lost from MA to HTA outcome across all drug-indication-country triplets (**England**: 5191; **Scotland**: 1334; **France**: 5371).



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References: 1. EFPIA WAIT Indicator 2024 Survey. 2025.