

Comparative Analysis of Oncology Therapy Approvals in the U.S. and Most Favored Nation Countries FPN 6454

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BACKGROUND & OBJECTIVE

Oncology therapies can provide substantial clinical benefit, but access may differ across countries because approval timing and labeled indications are not identical

This study compares approval timing and approved patient populations in the U.S. vs. selected MFN jurisdictions

METHODS

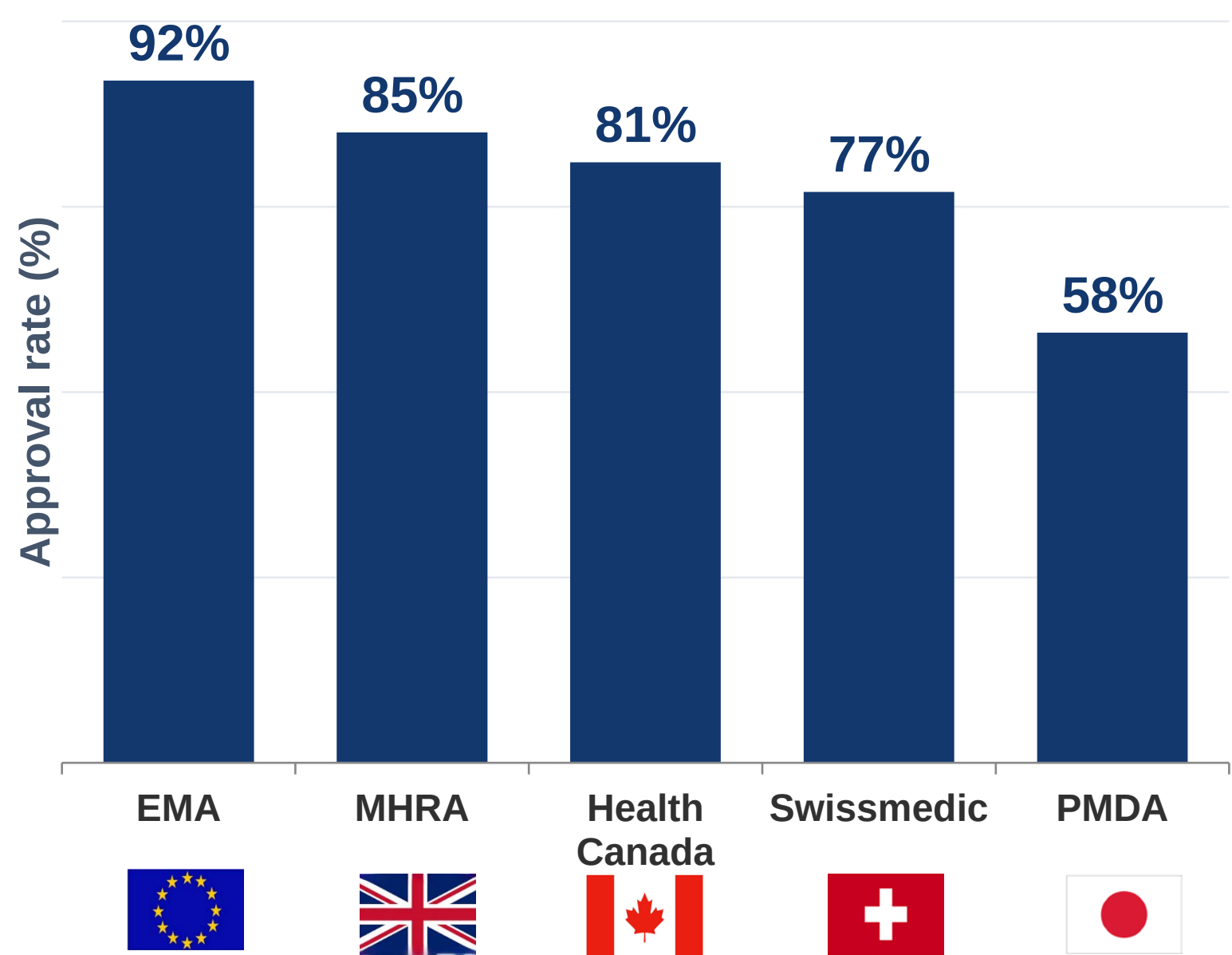
- Identified novel oncology approvals 2022-2023 from the FDA Novel Drug Approvals Database, limited to the drug's first approved indication
- Excluded non-malignant indications and supportive/adverse-effect management therapies
- MFN countries (CMS GENEROUS Model): Canada, Denmark, France, Germany, Italy, Japan, Switzerland, and the UK
- MFN-country approval dates and indications were obtained from Health Canada, EMA, PMDA, MHRA, and Swissmedic; data were current as of July 2026
- Two researchers independently compared labeled indications using a predefined checklist covering disease characteristics, prior-treatment requirements, treatment regimen, and other eligibility criteria
- Outcomes:** approval rate; approval lag (median months); indication concordance vs. the FDA label

RESULTS



26 Oncology therapies approved by the FDA in 2022-2023

Figure 1. Availability of FDA Oncology Approvals (2022-2023) Across MFN Jurisdictions



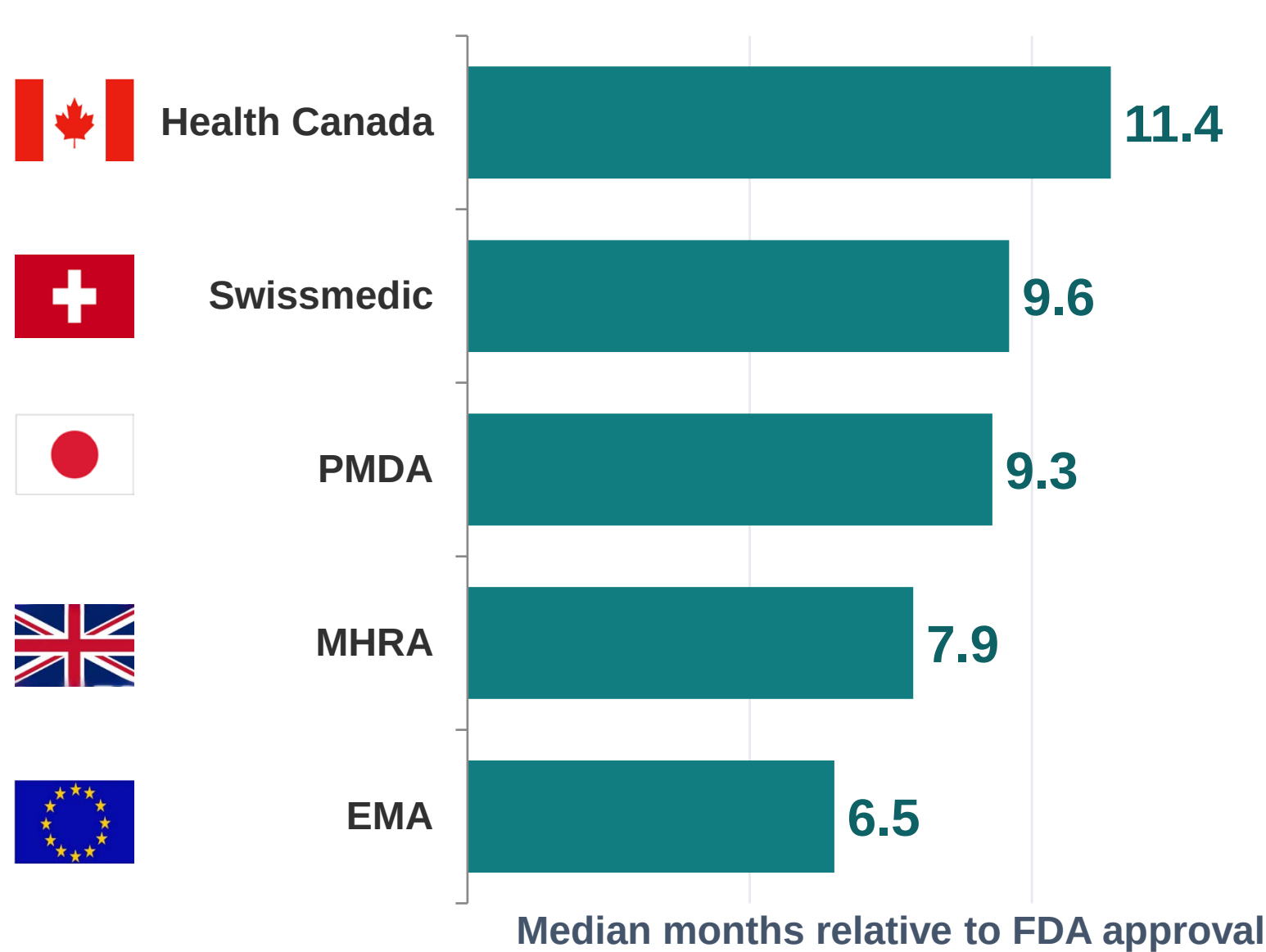
Approval rates ranged from 58% (15/26, PMDA) to 92% (24/26, EMA) across MFN jurisdictions



11.4 months

Longest median approval lag: Canada

Figure 2. Median Time to Approval Following FDA Approval Across MFN Jurisdictions

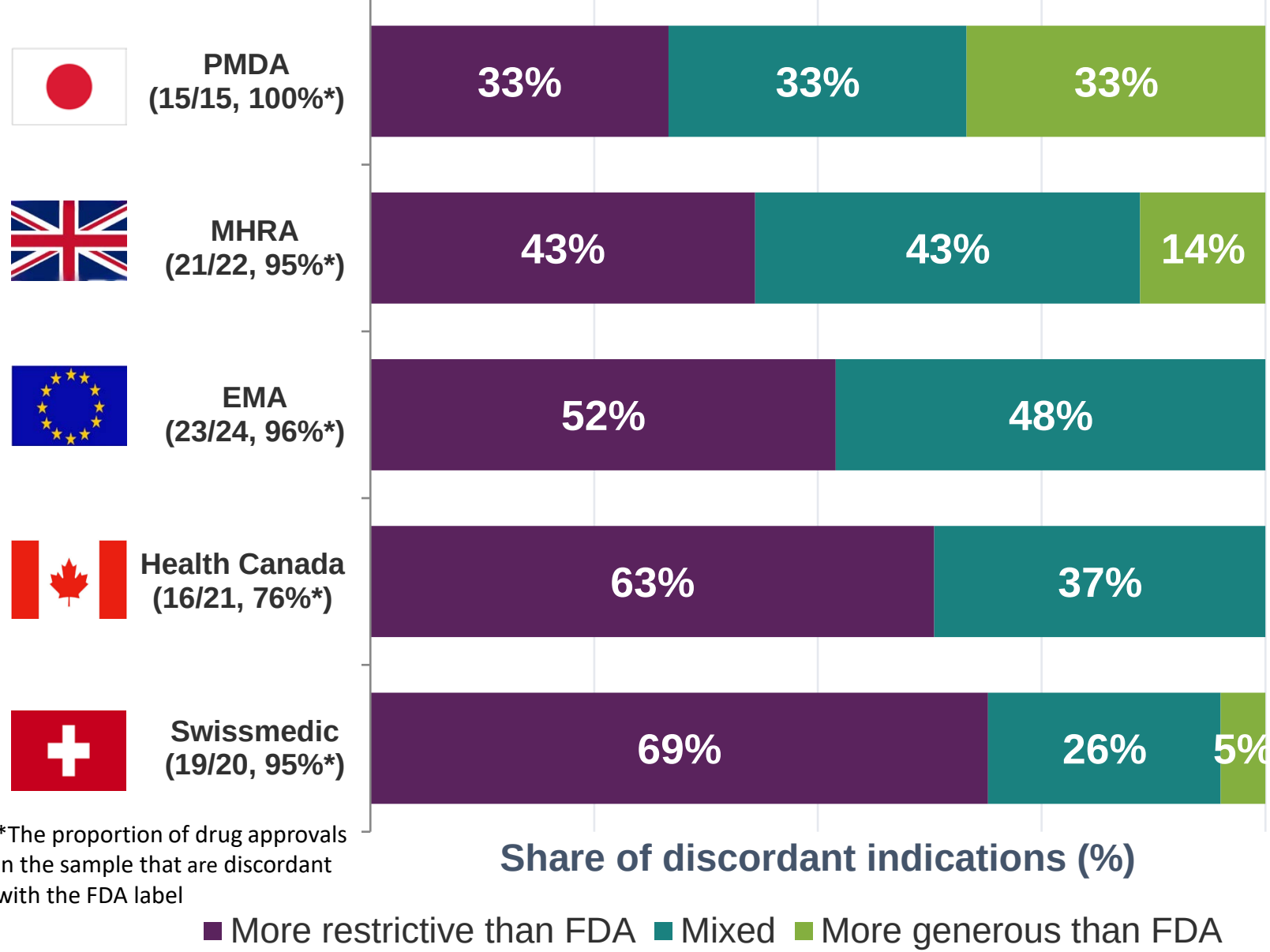


Median approval lag was longest in Canada (11.4 months) and shortest in the EU (6.5 months)



92% Of assessed indications discordant with the FDA label

Figure 3. Indication Discordance Relative to FDA Labeling by Regulator



92% of assessed indications were discordant with FDA labeling, most often more restrictive
Drivers:

- 77% prior-treatment requirements;
- 52% treatment regimen;
- 40% disease characteristics.

Note: Not mutually exclusive.

CONCLUSION

Substantial cross-national differences exist in the timing of oncology approvals and the patient populations covered by those approvals. These differences translate into variation in patient eligibility and access across MFN countries, with implications for policies that use these countries as international benchmarks.

FUNDING

This research was funded by AstraZeneca.

CONTACT

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