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

HPR183

Chambers J[1] , Knox S[1] , LaMountain F[1] , Liljas B[2] , Beinfeld M[1], Martin A[1]

1. Center for the Evaluation of Value and Risk in Health, Tufts Medical Center, Boston, MA, United States of America
2. Health Economics & Payer Evidence, Oncology, AstraZeneca USA, Gaithersburg, MD, United States of America

BACKGROUND & OBJECTIVE

Research has shown that oncology drugs are often first approved in the US and are generously covered.[1,2] However, it is uncertain how access compares across US and MFN countries.

This study compares regulatory approval timing, patient populations, and HTA-driven access across MFN countries versus the FDA

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
- Regulatory approvals, indications, and HTA decisions collected from official sources, current as of July 2026
- Outcomes: Approval rate, time to local approval, indication concordance, HTA status and recommendations

REGULATORY APPROVAL RESULTS

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

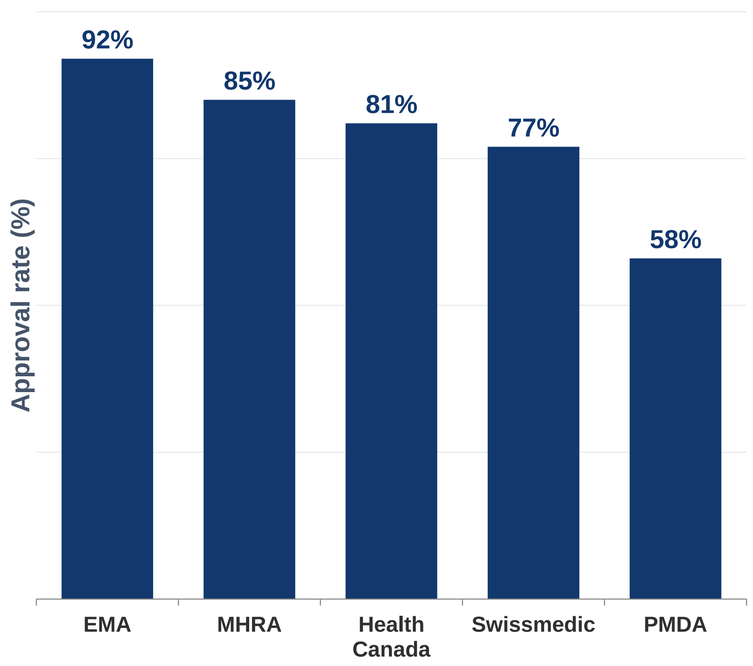
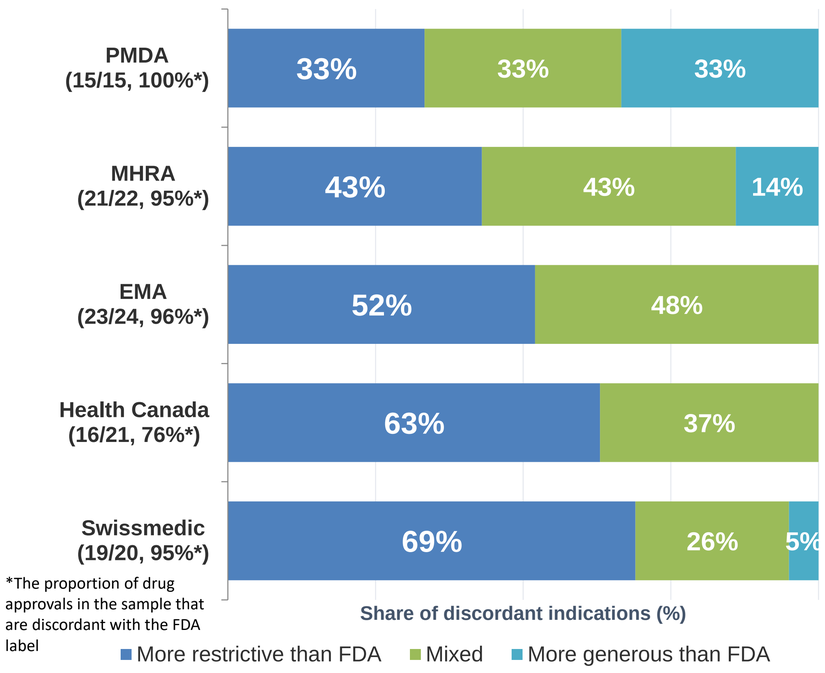


Figure 2. Indication Discordance Relative to FDA Labeling by Regulator



Across MFN jurisdictions approval rates ranged from 58% (15/26, PMDA) to 92% (24/26, EMA), with 79% of drugs approved across all jurisdictions.

92% of approved populations in MFN jurisdictions were discordant with FDA labeling, most often more restrictive

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

Note: Not mutually exclusive.

26 Oncology therapies approved by the FDA in 2022-2023

54% biologics • 89% expedited review designation

6.5 - 11.4 Median months from FDA approval to local regulatory approval

Fastest approval relative to FDA: EMA; slowest: Canada

92% Approved populations differed from FDA

Over half of MFN jurisdictions with discordant indications were more restrictive than the FDA-approved indication.

HEALTH TECHNOLOGY ASSESSMENT RESULTS

67% HTA completion across primary bodies

Ranged from 20% for C2H to 88% for HAS/TC

4.8 - 19.6 Median months from local regulatory approval to HTA completion

Mean of medians: 13.8 months; fastest CDA-AMC, slowest C2H

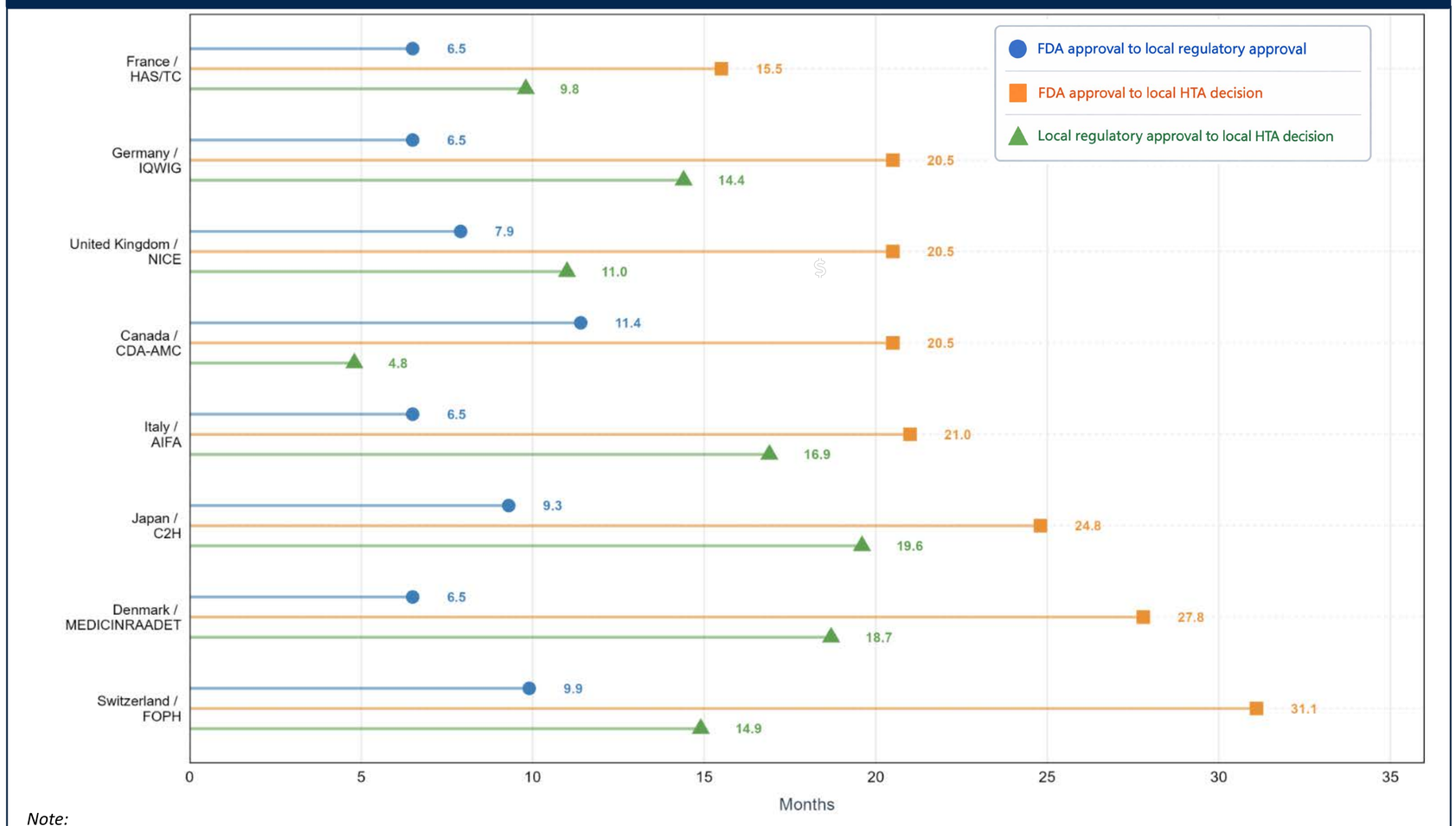
87% Recommended or Conditionally Recommended by HTA agency

106/122 completed assessments

49 Conditionally Recommended HTA decisions

- 20% clinical conditions
- 33% economic conditions
- 47% clinical AND economic Conditions

Figure 3. Median Regulatory and HTA Decision Timelines, by Country/Agency



Note:
EMA approved 24 drugs; HAS/TC assessed 21; IQWIG assessed 18; AIFA assessed 20; Medicinraadet assessed 16; MHRA approved 22; NICE assessed 17; Health Canada approved 21; CDA-AMC assessed 17; PMDA approved 15; C2H assessed 3; Swissmedic approved 20; FOPH assessed 7.

CONCLUSION

Regulatory approval and eligible patient populations for oncology therapies varied considerably across comparator countries. The U.S. demonstrated faster access to oncology therapies, while eligible populations in selected MFN countries often varied and were more restrictive than FDA-labeled indications.

REFERENCES

1. Lythgoe MP, Desai A, Gyawali B, Savage P, Krell J, Warner JL, Khaki AR. Cancer therapy approval timings, review speed, and publication of pivotal registration trials in the US and Europe, 2010-2019. *JAMA Netw Open*. 2022;5(6):e2216183.
2. Rucker JA, Beinfeld MT, Enright D, Liljas B, Chambers JD. Trends in utilization management for oncology therapies amongst US commercial health plans: 2017-2024. *JCO Oncol Pract*. Published online May 21, 2026.

Abbreviations: AIFA, Italian Medicines Agency; CDA-AMC, Canada's Drug Agency; CMS, Centers for Medicare & Medicaid Services; C2H, Center for Health Economics and Policy; EMA, European Medicines Agency; FDA, U.S. Food and Drug Administration; FOPH, Federal Office of Public Health; HAS/TC, Haute Autorité de Santé / Transparency Committee; HTA, Health Technology Assessment; IQWiG, Institute for Quality and Efficiency in Health Care; MFN, Most Favored Nation; MHRA, Medicines and Healthcare products Regulatory Agency; NICE, National Institute for Health and Care Excellence; PMDA, Pharmaceuticals and Medical Devices Agency; UK, United Kingdom; US, United States.

Acknowledgements: We gratefully acknowledge Jon Campbell, Wolfgang Greiner, Eric Low, Peter Neumann, Dan Ollendorf, Oriol Sola-Morales, and Lotte Steuten for their valuable guidance and input on the study design.

Funding : This research was funded by **AstraZeneca**.

Contact: For more information, please contact James Chambers at james.chambers@tuftsmedicine.org.