Poster Code: HPR161

International Comparisons of Health Technology Assessment and Reimbursement Outcomes for Oncology Drugs with Regulatory Review through Project Orbis

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Objectives

- Project Orbis is an international regulatory collaboration led by the US Food and Drug Administration (FDA) Oncology Center of Excellence
- The program enables concurrent regulatory review of oncology products, with aim to give patients faster access to promising cancer treatments
- We examined health technology assessment (HTA) and public reimbursement outcomes for Project Orbis drug-indications reviewed in Canada and other jurisdictions globally

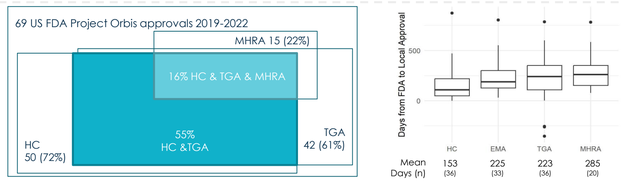
Methods

- We identified and assessed concordance in regulatory approvals for Project Orbis drugs approved by Project partners: Canada, Australia, (and UK) from program inception in 2019 to end of 2022
- For drug-indications with an HTA submission in Canada, we collected all related HTA recommendations and reimbursement outcomes for the three countries plus France, Germany up to March 2023, classifying all non-negative reimbursement recommendations as positive, listed in at least one Canadian province as funded
- We determined concordance in HTA submissions, recommendation statuses, recommendation outcomes, and in public funding status across jurisdictions
- We assessed time from FDA approval to regulatory approvals and completed HTA dates in each jurisdiction

Limitations

- Reliance on publicly available data, with some limitations (e.g., UK funding assumed 90 days from HTA conclusion for funding comparison)
- Limited scope (regulatory approval with CADTH submission); full Project scope could differ
- Early access at or ahead of market approval in Germany and France preclude time-to-listing assessment similar to other jurisdictions; subsequent market changes not captured

Regulatory Approvals



- Most US FDA approvals through Project Orbis in 2019-22 were also approved by Canada or Australia
- Participation by partners on each approval differed, resulting in variation in time to approval and lower international consistency

Note: UK joined Project Orbis in 2021

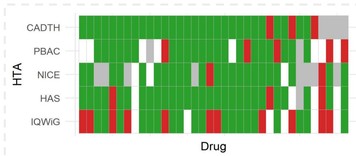
Jurisdictional Details and Differences

	Canada	Australia	United Kingdom	France	Germany
Project Orbis Partner	Yes	Yes	Yes (Jan/21)	No	No
Regulatory Agency	HC: Health Canada	TGA: Therapeutic Goods Administration	MHRA: Medicines and Healthcare products Regulatory Agency (Feb/20)	EMA: European Medicines Agency	EMA: European Medicines Agency
HTA Agency	CADTH	PBAC	NICE	HAS	IQWiG
Specific system, policy or legislative considerations for funding	**CADTH has no access to net prices, does not participate in reimbursement**/ pricing (confidential) negotiations that mostly occur after HTA completion. There is **no formal pathway to accelerate negotiation**, and pre-regulatory HTA submission is permitted but only 39% of Project Orbis drugs leveraged this. 14 different provinces/ territories have autonomy in when to fund the drug following successful joint negotiation (often significantly different between first and last to fund).	**PBAC can render "not recommended" decision based on cost-effectiveness, but if there is clinical merit can ask for risk-sharing arrangement that includes confidential pricing terms for resubmission.** A price offer package must be submitted by manufacturer within 6 months of positive PBAC recommendation and federal Department of Health can further negotiate to execute reimbursement agreement.	**When NICE recommends a treatment 'as an option', NHS England must make it available within 3 months** (unless otherwise specified) of its date of publication. There are various mechanisms to facilitate access (e.g., Accelerated Access Review). **NICE can take into account confidential prices in its evaluation**, and negotiations can occur during HTA review. Cancer Drug Fund allows for Managed Entry with RWE collection, with a category cap in place.	**There is an early access pathway** (autorisation temporaire d'utilisation, ATU), which was granted for many Project Orbis drug-indications; **price negotiations and final reimbursement decision can occur after initial funding.** Economic evaluation is conducted separate from HTA clinical evaluation only for drugs likely to have a significant budget impact and is taken into consideration for confidential pricing negotiation by the federal Ministry.	Funded at market entry prior to HTA evaluation and price negotiation/ adjustments. **Drugs are reimbursed by default in Germany**: companies may launch with reimbursement and at a price of their choosing as soon as they receive marketing authorization. **Unfavourable IQWiG/G-BA outcome or low expected negotiated reimbursement price** (which becomes publicly available) **could lead to market withdrawal.**

CADTH: Canadian Agency for Drugs and Technologies in Health; PBAC: Pharmaceutical Benefits Advisory Committee; NICE: National Institute of Health and Care Excellence; HAS: Haute Autorité de santé, IQWiG: Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Healthcare)

HTA Outcomes

Among Project Orbis drug-indications with Canadian and Australian regulatory approvals, 36 have been submitted to CADTH

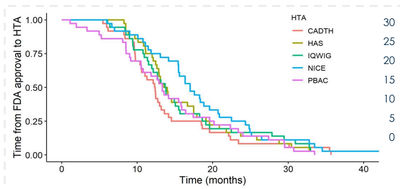


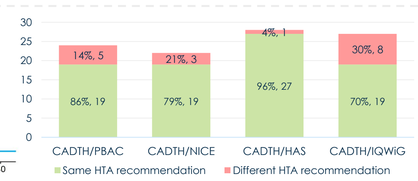
Percent agreement in HTA status between countries

	CADTH	PBAC	NICE	HAS	IQWiG
CADTH	-	67%	64%	78%	75%
PBAC	67%	-	56%	75%	67%
NICE	64%	56%	-	75%	69%
HAS	78%	75%	72%	-	86%
IQWIG	75%	67%	69%	86%	-

Similarity in HTA status: HTA status (completed, in progress or not submitted), varies across drug-indications between countries, resulting in moderate concordance in current HTA status overall

- More similarity between CADTH and EU than with NICE or PBAC

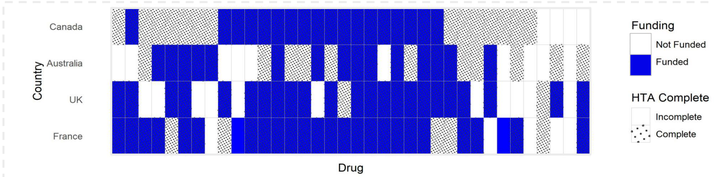




Similarity in HTA recommendations: Among reviews with final recommendations issued, majority(~80%) of drug-indications have concordant outcomes (mainly positive) across HTA

- Time from FDA to HTA recommendation similar across jurisdictions
- Drug-indications submitted to multiple HTA agencies likely to consistently receive positive recommendation

Funding



Percent agreement in funding status across jurisdictions

	Canada	Australia	UK	France
Canada	-	53%	69%	67%
Australia	53%	-	50%	42%
UK	69%	50%	-	58%
France	67%	42%	58%	-
Completed HTA	32	26	25	29
% Funded	56%	58%	92%	83%

- Wide variation (22% overall agreement) in funding across countries for included drug-indications
- Most similarity between Canada and UK, France in funding status

- Among drug-indications with completed HTA, much lower proportion funded in Canada and Australia

Conclusions

- High variability in market access routes and timelines for drug-indications approved through Project Orbis internationally
- Many factors affect reimbursement decisions and timelines to patient access, including differences in systems, policies, and processes (regulatory, HTA, pricing negotiations) among jurisdictions, which contribute to differences in access
- Challenging to fully capture and attribute benefits of collaborative regulatory review; timelines depend on starting point

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