How does the Japan CE-HTA compare with ROW

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Introduction

- In Japan, since April 2019 selected pharmaceutical products and medical devices have required health technology assessment (HTA) of their cost-effectiveness (CE) by the Central Social Insurance Medical Council (Chuikyo), from which list-price adjustments are made
- This formal HTA process was implemented in response to unsustainable healthcare costs, with Japan having some of the highest drug costs outside the US
- This research compares the CE outcomes of the first two pharmaceutical products that have been assessed in Japan (Kymriah and Trelegy in July 2021) with those from other countries that use CE as a key decision-making criterion

Methods

- Publicly-accessible assessments of Kymriah and Trelegy by six CE-HTA bodies (Chuikyo, NICE, SMC, CADTH, PBAC/MSAC) up to June 2021 were extracted and compared

Results

- Chuikyo's ICER threshold per QALY is €38k-€76k compared to €23k-€35k for NICE, while SMC, CADTH and PBAC/MSAC do not have any explicit ICER thresholds
- Fluticasone/umeclidinium/vilanterol (Trelegy, H1-category [newly-listed product with peak annual sales ≥¥10 billion]) and tisagenlecleucel (Kymriah, H3-category [newly-listed product with notably high price or requiring re-evaluation due to new robust evidence being discovered]), were both recommended by Chuikyo for list price reductions based on their CE:
    - Trelegy -0.5%,
    - Kymriah -4.3%
- **Trelegy** was stratified by Chuikyo into 12 sub-populations for COPD and pulmonary emphysema, with only three sub-populations deemed cost-effective with added benefit and ICERs between €2.5k-€14k
    - NICE has not yet appraised Trelegy, while SMC, CADTH and PBAC have all restricted their recommendations to specific sub-populations
- **Kymriah** was stratified by Chuikyo into three sub-populations for B-ALL (ICER €17k-€21k), and two sub-populations for DLBCL (ICER €61k-€95k)
    - NICE has recommended both indications for the CDF, whilst SMC has recommended both with PASs. CADTH has given both conditional recommendations requiring price reduction. Finally, MSAC has recommended both using risk-sharing agreements.

Table 1: Comparing Chuikyo HTA outcomes with other cost-effectiveness markets

Country	HTA body	HTA outcome	
		Trelegy (COPD & emphysema**)**	**Kymriah** (ALL & DLBCL)
Japan	**Chuikyo**	**H1-category Price reduction: -0.5%**	**H3-category Price reduction -4.3%**
Comparison to other HTA bodies			
England	**NICE**	Not assessed	Cancer Drugs Fund
Scotland	**SMC**	Restricted	Patient Access Scheme
Canada	**CADTH**	Restricted	Price reduction
Australia	**PBAC / MSAC**	Restricted	Risk-sharing agreement

Reimbursement key: **Positive** **Restricted/Conditional** **Negative** **Not assessed**

Conclusions

- The first two products to be subject to CE evaluation in Japan have not been deemed acceptably cost-effective and price reductions have been demanded
- These products have also had challenges in being deemed cost-effective in other mandatory cost/QALY markets based on the evidence at submission

Abbreviations: ALL, Acute Lymphoblastic Leukemia; **CADTH**, Canadian Agency for Drugs and Technologies in Health; **CDF**, Cancer Drugs Fund; **COPD**, Chronic Obstructive Pulmonary Disease; **DLBCL**, Diffuse Large B-cell Lymphoma; **HTA**, Health Technology Assessment; **ICER**, Incremental Cost-Effectiveness Ratio; **NICE**, National Institute for Health and Care Excellence; **PAS**, Patient Access Scheme; **PBAC/MSAC**, Pharmaceutical Benefits Advisory Committee/ Medical Services Advisory Committee; **QALY**, Quality-Adjusted Life Year; **SMC**, Scottish Medicines Consortium

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