# Investigation of factors considered in the Health Technology Assessment conducted by regulatory authorities in eight countries



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# **INTRODUCTION**

Health Technology Assessment (HTA) organizations play a crucial role in optimizing the healthcare resources and using the budget allocated for its medical care sector. Recommendations made by HTA organizations may vary across countries for a single intervention. Hence, analyzing the factors considered by different HTA organizations on the decision-making becomes important.

# **OBJECTIVES**

To understand the differences in the process and factors involved in decision-making by HTA organizations across eight countries.

# **METHODS**

A targeted literature review (TLR) was conducted from two sources for HTAs that were evaluated up until August 2019 – HTA Accelerator (HTAA; IQVIA's HTA dossier literature platform) and evidence or dossiers available on HTA organizations' webpage. Descriptive statistics were used to measure the frequencies and correspondence analysis was conducted.

#### Table 1. Data evaluated in the present study

Population/Intervention/comparison/outcome/study design (PICOS) criteria		Number of dossiers included per HIA organization			
Target drugs	Hepatitis C: Daklinza <sup>®</sup> , Sunvepra <sup>®</sup> , Viekirax <sup>®</sup> , Harvoni <sup>®</sup> , Sovaldi <sup>®</sup> Cancer: Opdivo <sup>®</sup> , Keytruda <sup>®</sup> , Kadcyla <sup>®</sup> , Ibrance <sup>®</sup> AFTSA (Spain) AIFA (Italy) C2H/Chuikyo* referred to as C2H (Japan) CADTH/pCODB**	Organization	Cancer	Hepatitis C	Total
organizations	(Canada), HAS (France), IQWiG (Germany), NICE (UK), PBAC (Australia),				
<section-header></section-header>	Economic evaluations: Incremental cost-effectiveness ratio (ICER) with QALY, cost only, not available	AETSA	5	7#	12
	<b>Clinical uncertainties and issues:</b> clinical benefit, comparator, population and generalizability, safety, sample size and study design	AIFA	8	0	8
		CADTH/pCODR	21	7	28
	<b>Disease considerations:</b> disease nature/severity, end of life, rare/orphan status, national	C2H	2	5	7
	priority	HAS	22	7	29
	Population considerations: children, disadvantaged population and stakeholder persuasion	IQWiG	23	6	29
		NICE	23	2	25
	<b>Treatment considerations:</b> complex pathways, innovation, indirect benefit from the treatment issues around current alternative treatment, manageable/non-significant	PBAC	43	8##	51
	adverse events ( $\Delta Fs$ ) and unmet needs	Total	147	42	189
	<b>Future elements of value (suggested by ISPOR special task force):</b> adherence-improving factors, equity, fear of contagion, insurance value, real option value, scientific spillovers, value of reduction of uncertainty due to a new diagnostic and value of hope	*Due to recent changes in the organization of HTAs in Japan, documents from both C2H and Chuikyo documents were used as references **In Canada, cancer technologies are evaluated by pCODR and other diseases are evaluated by CADTH #Daklinza, Exviera, Harvoni, Holkira Pak, Olysio, Sovaldi, Viekirax are evaluated in			

# RESULTS

### **Economic evaluations**

- Irrespective of the disease, all or most dossiers by the NICE, the CADTH/pCODR, the C2H and the PBAC used ICER with QALY

#### **Consideration factors**

- The NICE is the only organization to report end-of-life and rare/orphan status; and nearly all factors related to treatment considerations
- considerations, population ♦ For

#### Figure 1. Economic evaluation types by HTA organization and disease

##Daklinza and Sunvepra are evaluated in one dossier for PBAC

one dossier for AETSA



• For the IQWIG, all cancerrelated dossiers were evaluated using cost only analysis. For the HAS, about 55% of dossiers showed costeffectiveness analysis using ICER with QALY (Figure 1)

## **Clinical uncertainties and** issues

- For cancer, the highest number of uncertainties observed were related to clinical benefits followed by comparator while the reported issues across organizations were variable (Figure 2)
- For Hepatitis C, similar trends as cancer dossiers were observed.

#### elements of Future

stakeholder persuasion and unmet were the most common needs reported factors HTA across organizations

Correspondence analysis showed the most common attributes observed were unmet needs, stakeholder persuasion, disease nature/severity and indirect benefit. The NICE was distinguished from other organizations for noting additional factors, such as issues around alternative treatment, end-of-life and innovation. The IQWiG, on the other hand, was uniquely associated with manageable or non-significant AEs (Figure 3)

**Figure 3. Correspondence analysis for** cancer drug evaluation consideration factors

Manageable/non-**AIFA** sig. AEs Innovation Unmet needs HAS



- The PBAC mentioned the most number of additional factors recommended by **ISPOR's Special Task Force**
- The most common additional elements of value considered by the PBAC included fear of contagion, equity and scientific spillover (Figure 4)

**IQWiG** 

PBAC 🔺 🦻

.6%)

(21

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# Discussion

Due to limitations to publicly available information in HTA dossiers, the study could not Due to the small sample size no  $\blacklozenge$ determine which factors were included/absent with certainty for decision-making definite observations are made

# Conclusion

- Although clinical factors play a predominant role in the decision to reimburse medicine, the NICE and the PBAC were found to be the HTA organizations with the most comprehensive list of additional criteria
- If the decision-making process of HTA were clearly outlined with more transparency into the considered factors, there would be more transparency in HTA systems leading to better understanding amongst stakeholders about decision-making

Abbreviations: AETSA: Agencia de Evaluación de Tecnologías Sanitarias de Andalucía; AIFA: Agenzia Italiana del Farmaco; CADTH/pCODR: Canadian Agency for Drugs and Technologies in Health/pan-Canadian Oncology Drug Review; C2H: Center for Outcomes Research and Economic Evaluation for Health/Central Social Insurance Medical Council; HAS: Haute Autorité de Santé; IQWiG: Institute for Quality and Efficiency in Healthcare; ISPOR: International Society for Pharmacoeconomics and Outcomes Research; NICE: National Institute for Health and Clinical Excellence; PBAC: Pharmaceutical Benefits Advisory Committee; QALY: quality-adjusted life years

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