HOW WIDE RANGING IS THE IMPLEMENTATION OF HTA AND COST-EFFECTIVENESS ASSESSMENT (CEA) IN MAJOR HEALTHCARE MARKETS

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INTRODUCTION

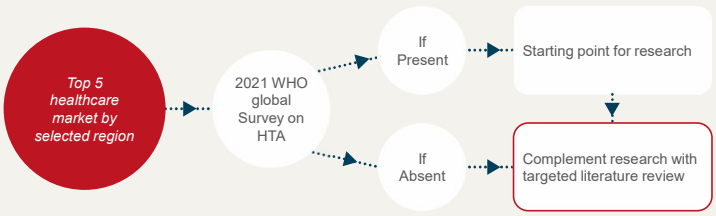
- In 2014, Resolution 67.23 of the World Health Assembly urged member states to consider establishing Health Technology Assessment (HTA) processes in support of universal healthcare.
- Since 2015, the WHO has been releasing reports to track the implementation of HTA across member states (via the 2015[2] and 2021[1] WHO global HTA report).
- HTA aims to establish a rigorous assessment of health technologies, usually via a combination of scientific and economic assessment, and pricing negotiation.
- HTA can include cost-effectiveness and added benefit assessments.
- Cost-effectiveness assessment considers the clinical effectiveness and cost of the innovative drug compared to the comparator; and pricing negotiations are framed on a defined willingness to pay threshold. The first country to develop cost-effectiveness assessment was Sweden in 1993[3].
- Added benefit assessment rates the level of additional clinical effectiveness of a technology compared with the standard of care; and pricing negotiations are framed based on the added benefit rating. Germany and France are the most notable countries using this type of assessment.

OBJECTIVE(S)

- Review the implementation of HTA processes across the largest markets in each region and how cost-effectiveness assessment mechanisms are distributed amongst these countries.

METHODS

- Top five healthcare markets by estimated size (revenues and population) were identified in the following regions (Americas, Europe, APAC, Rest of the world). (**Table 1**)
- The 2021 WHO Global Survey on HTA and Health Benefit Packages report was used as a starting point to identify the countries with established HTA process; the availability of national guidelines for the preparation of economic evaluation; and whether CE assessment was used for decision making for reimbursement.
- Any missing information was supplemented through targeted literature review.



DISCUSSION

- There is global interest in the implementation of HTAs to support universal healthcare. This is made explicit by WHO efforts to product the HTA global survey report, and the demonstrated increase in response rate between surveys.
- Additionally, in the last 10 years, countries like China[4], The Phillipines[5] and Kenya[6] have introduced HTA processes for reimbursement decisions.
- USA is the notable exception to the global interest in HTA. The lack of universal healthcare may contribute to the lack of national HTA. Instead, non-governmental organisations like the Institute for Clinical and Economic Review (ICER) provide independent, nonprofit, nonpartisan research on pharmaco-economic assessment of health technologies.
- Countries that use CE assessment may also consider budget impact in reimbursement decision-making; although this was not analysed here.
- Only two reviewed markets (Spain and UK) have published their willingness to pay thresholds. It is possible that other markets do not do so to provide them with more flexibility in the decision-making process when the introduction of a product could have budget impact implications.

RESULTS

- There was a 13% increase in response rate to the WHO survey from 2015 to 2021 (111 to 125 countries).
- As of 2021, 95% (19 of 20) of markets had established an HTA process to support healthcare decision-making. (**Table 2**)
- The majority (79%) of the countries with HTA (15 of 19) have established national guidelines for economic evaluation assessment. (**Table 2**)
- Cost-effectiveness assessments (CEA) are the most common pharmaco-economic tools used for healthcare decision making across the globe, with 74% of the reviewed countries with HTA (14 of 19) conducting CEA (**Table 2**)
- However, only two (Spain and United Kingdom) publicly define the willingness to pay threshold use for medicines reimbursement decisions.
  - In Spain the threshold is between €20,000-25,0000, and in UK between £20,000-30,000[1]

Table 1 Healthcare markets selected by region

Americas	Europe	APAC	Rest of the world
Argentina	France	Australia	Malaysia
Brazil	Germany	China	Russia
Canada	Italy	India	Saudi Arabia
Mexico	Spain	Japan	South Africa
USA	UK	South Korea	Turkey

Table 2 Review of HTA processes in selected countries

Countries	Region	Formal HTA Process?	Guidelines for economic evaluations?	Do they use CE evaluation?	Explicit CE Threshold?
Argentina	Americas	Yes	No	No	No
Australia	APAC	Yes	Yes	Yes	No
Brazil	Americas	Yes	Yes	Yes	No
Canada	Americas	Yes	Yes	Yes	No
China	APAC	Yes	Yes	Yes	No
France	EU	Yes	Yes	No	No
Germany	EU	Yes	No	No	No
India	APAC	Yes	No	No	No
Italy	EU	Yes	Yes	Yes	No
Japan	APAC	Yes	Yes	Yes	No
Malaysia	ROW	Yes	Yes	Yes	No
Mexico	Americas	Yes	Yes	Yes	No
Russia	ROW	Yes	Yes	Yes	No
Saudi Arabia	ROW	Yes	No	Yes	No
South Africa	ROW	Yes	Yes	No	No
South Korea	APAC	Yes	Yes	Yes	No
Spain	EU	Yes	Yes	Yes	Yes
Turkey	ROW	Yes	Yes	Yes	No
UK	EU	Yes	Yes	Yes	Yes
USA	Americas	No	No	No	No

Abbreviation, HTA: health technology Assessment; CE: Cost-effectiveness; APAC: Asia Pacific; ROW: Rest of the world; EU: European Union

CONCLUSIONS

- Interest in HTA by global markets increased between 2015 and 2021.
- Majority of large healthcare markets by region have already implemented HTA processes to support decision-making.
- Cost-effectiveness assessments are common in HTAs, with over 70% of the largest markets utilising CEA.
- Given this, it would be interesting to understand the influence of established CE countries like Australia, Sweden and UK on assessments in other less established CE assessment markets.
- Future research is needed to understand the progression of HTA implementation across global markets, as well as the level of influence established CEA HTAs have on the newly developed HTAs processes on other global markets.

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