# HTA Processes for Medical Technologies Across the World: Are All Hurdles the Same?

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## BACKGROUND

- Health technology assessment (HTA) is increasingly being used to assess nonpharmaceutical medical technologies such as medical devices, diagnostics, and digital or wearable health technologies.
- HTA processes and requirements can vary among authorities around the world. They can also vary within an authority, with different HTA pathways or channels used depending on the type of health technology being considered.
- Navigating the differences between regional HTA agencies has implications for strategic decision-making and poses a challenge for developers of nonpharmaceutical medical technologies.

## OBJECTIVE

- To explore HTA processes for medical technologies and evaluate similarities/differences by continent.

## METHODS

- The guidelines and process documents for HTA evaluations in 5 continents were reviewed through December 2022.
- Qualitative data from Europe, North America, South America, Asia, and Oceania were obtained using primary and secondary data from direct communication with HTA authorities, HTA websites, and reports.
- These data were collated in Excel and compared by continent.

## RESULTS

**Table 1. Requirements for Medical Technology HTA Across the Continents**

| North America[1] | South America[2-3] | Europe[4-15] | Asia[16-23] | Oceania[24] | Comment |
|---|---|---|---|---|---|
| **How is medical technology assessed?** | | | | | |
| General HTA process (i.e., same as for pharmaceutical or other health technologies) | Unclear | Specific processes for medical technologies can be found in the UK, France, Belgium, Italy, Scotland, and Sweden. | General HTA process (i.e., same as for pharmaceutical or other health technologies) | General HTA process (i.e., same as for pharmaceutical or other health technologies) | Except for Europe, medical technologies were assessed in a general HTA program where assessments for medical technologies were the same as for pharmaceutical or other health technologies. |
| **Is there a specific-submission template for medical technology companies to provide information to the HTA body?** | | | | | |
| Yes, varies by country | Unclear | Yes, varies by country | Yes, varies by country | Yes, varies by country | Templates are country specific. |
| **Are economic evaluations included in HTA evaluation?** | | | | | |
| Yes | Unclear | Yes | Unclear | Yes | Most continents include economic evaluations as part of the HTA assessment. |
| **What economic methods are considered in HTA evaluation?** | | | | | |
| Cost-utility analysis | Unclear | Cost-utility, cost-effectiveness, cost-minimization, budget impact | Cost-effectiveness (based on device value); budget impact | Cost-utility | The specific analysis of choice varies by country and depends on type of technology, available evidence, and company pricing strategy. |
| **What is the primary outcome for economic evidence?** | | | | | |
| QALY, LYG, cost | Unclear | QALY, LYG, other health-related effects, cost | Unclear | QALY, LYG, cost | In continents where information was available, QALY, LYG, and cost are all key economic outcome measures. |
| **What perspective is used for economic evaluation?** | | | | | |
| Societal | Unclear | Range from societal to healthcare system | Unclear | Healthcare system | Europe: country-specific definitions of societal, limited societal, extended healthcare, healthcare, publicly funded health, and social care. |
| **What are HTA review times?** | | | | | |
| 30 days | 180 days | 3-6+ months | 8-18 months | Unclear | HTA review times vary across and within continents |

LYG = life-year gained; QALY = quality-adjusted life-year.

## DISCUSSION

- Rapid growth in the aging population, an increase in chronic, lifestyle-related illnesses, and the introduction of new and expensive health technologies indicate that demands on health services are growing and that the need to prioritize will continue to escalate.
- Pharmaceuticals have been evaluated for some time, and there is a clear trend for medical devices to follow.
  - In the UK, the National Institute for Health and Care Excellence (NICE) established a specific evaluation process for medical devices in 2009.[25]
  - In 2020, Sweden initiated a national collaboration for the evaluation and introduction of medical technology.[26]
  - In 2021, the European Union introduced new directives and regulations to the market to standardize assessment for medical technologies.[27]
- As seen in the above results, HTA process may vary by and within continent, and Europe is the forerunner in the process of HTA evaluation of medical devices.
- Medical technology companies need to consider their market access strategy early and include a plan for health economic assessment in order to be relevant in a competitive space. This should include collecting outcome data that are relevant for the product's intended position in the patient pathway.
- While HTA processes differ across markets, there are some common hurdles that need to be addressed.
- Apart from variation in the HTA processes between jurisdictions, the intended use of HTA varies, ranging from decision-making for reimbursement to pricing.
- Because there is no legal requirement to demonstrate clinical benefit at the regulatory/licensing stage for medical technologies, the available evidence may not be high enough to meet typical HTA standards.[28] However, in the absence of robust clinical evidence for medical technologies, the minimum standard of evidence required by HTA bodies may vary.
- Any plans for the development of clinical evidence may need to be agreed upon with HTA bodies. Moreover, NICE considers HTA-relevant outcomes like costs and QALYs retrieved from non-randomized controlled trial data.[29]

## HURDLES TO OVERCOME

### Limited data

As the data available for medical technologies are often limited, manufacturers need to consider how best to leverage the data that are available in their submissions.

### Economic models

Requirements vary across continents in terms of the economic approach.

- The cost of developing economic model versus potential gain of nationwide market access (or loss of market shares) must be considered.

### Literature reviews

Requirements vary across continents. Most national HTA agencies require rigorous clinical systematic literature reviews (SLRs), and some require economic SLRs.[30]

- Some countries in the European Union need SLRs updated within 6-12 months of submission.

### Confidential data

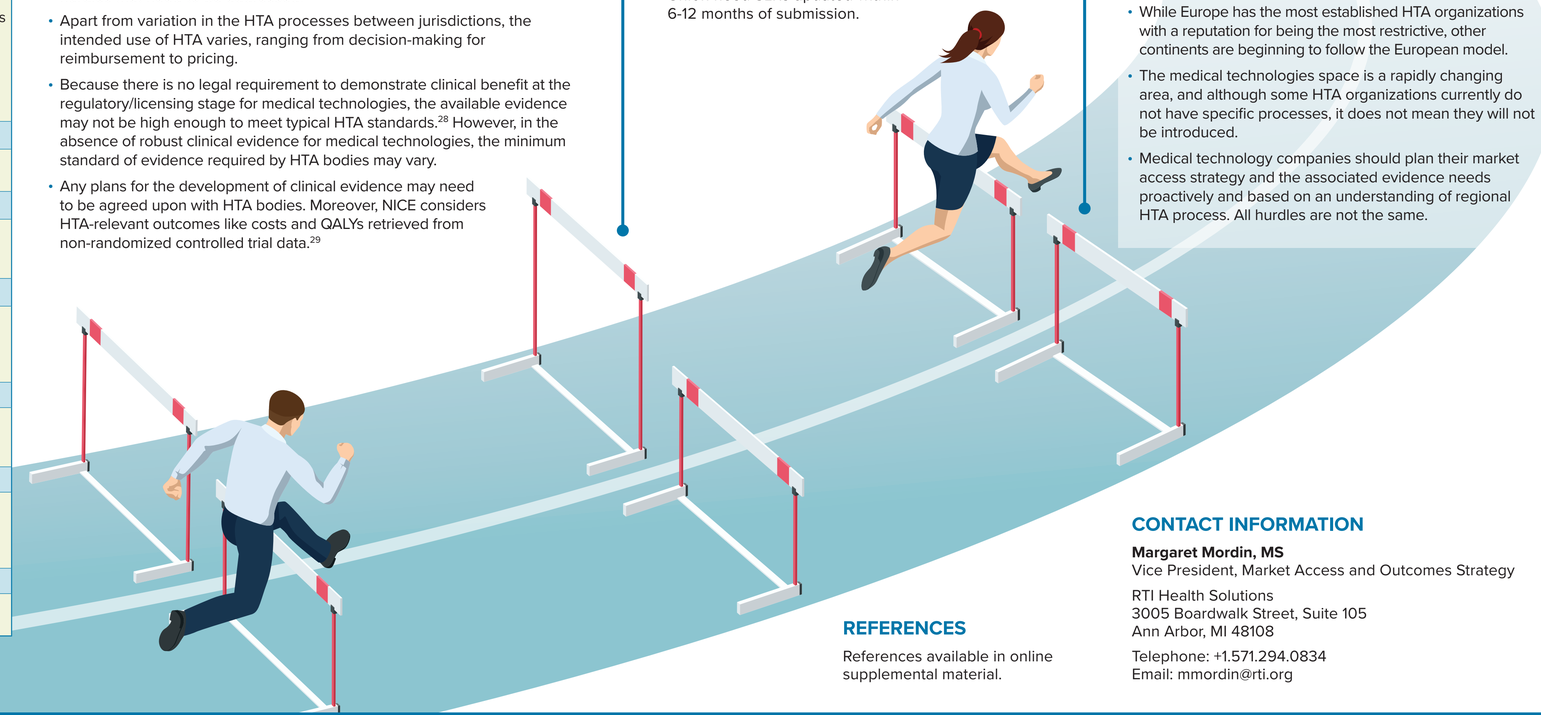
Not accepted for decision-making within some continents.

- Think about an evidence-generation strategy, and do not rely on "data on file."

### Submission strategy

The manufacturer should use knowledge of its data, any gaps, and the timing of availability of new evidence along with HTA organization approach to prioritize the order and content of submissions.

- One option is to start with HTA bodies with shorter review times and share those submissions with other countries.
- Alternatively, start with NICE as it has the potential to have a positive impact both within and outside the UK.[3]



## CONCLUSIONS

- HTA processes vary by and within continents.
- While Europe has the most established HTA organizations with a reputation for being the most restrictive, other continents are beginning to follow the European model.
- The medical technologies space is a rapidly changing area, and although some HTA organizations currently do not have specific processes, it does not mean they will not be introduced.
- Medical technology companies should plan their market access strategy and the associated evidence needs proactively and based on an understanding of regional HTA process. All hurdles are not the same.

## REFERENCES

References available in online supplemental material.

## CONTACT INFORMATION

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