Process and Requirements for Submitting Nonpharmaceutical Medical Technologies to Health Technology Assessment Authorities

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BACKGROUND

- Health technology assessment (HTA) is being increasingly used to assess nonpharmaceutical medical technologies such as medical devices, diagnostics, and digital or wearable health technologies.
- HTA processes and requirements can vary between authorities around the world. It 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 and within HTA agencies affects strategic decisions and poses a challenge for developers of nonpharmaceutical medical technologies.

OBJECTIVE

- To explore differences between HTA authorities in terms of evaluation processes and requirements for medical technologies in 20 countries and to suggest the most efficient and cost-effective market access strategy.

METHODS

- The guidelines and process documents for HTA evaluations in 20 countries were reviewed up to June 2022.
- Information from 13 countries from Europe (Austria, Belgium, Denmark, France, Italy, Norway, Portugal, Republic of Ireland, Scotland, Spain, Sweden, The Netherlands, United Kingdom [England and Wales]), 1 from North America (Canada), 2 from South America (Brazil, Uruguay), 3 from Asia (Japan, Malaysia, South Korea), and 1 from Oceania (Australia) was obtained using primary and secondary data from direct communication with HTA authorities, HTA websites, and reports.
- Qualitative data were obtained and collated in Excel. The processes and requirements of each authority were compared.

RESULTS

- Of the 20 included countries, 1 had no HTA process for nonpharmaceutical medical technologies (Uruguay). However, in Uruguay, for some highly specialized medical procedures, the National Resources Fund (FNR), an institution created by Decree-Law 14,897 as a nonstate public entity, provides financial coverage to the users of the National Integrated Healthcare System.[1] Therefore results are based on information from 19 countries.
- Of the 19 countries assessed, 5 had an HTA process dedicated to medical technologies (Australia, Belgium, France, Scotland, and Sweden).[2-6] Dedicated assessments use different process or methods than other types of health technology (such as pharmaceuticals).
  - For 9 countries (Canada, Denmark, Japan, Malaysia, Norway, Portugal, Republic of Ireland, South Korea, and The Netherlands),[2,7-16] medical technologies were assessed in a general HTA programme where assessments for medical technologies are the same as for pharmaceutical or other health technologies.
  - For 2 countries, medical technologies could be assessed in either a dedicated or general assessment programme (Italy and UK).[17-20]
  - For 3 countries (Austria, Brazil, and Spain),[2,21,22] it was unclear whether HTA for medical technologies was the same as or different than for other health technologies.
- Company submissions were allowed in 10 countries.
  - 4 countries had HTA authorities that specifically state that a company submission is not required.
  - For 5 countries, it is unclear whether a submission is required.
  - 5 countries allow consideration of unpublished or confidential information.
- For a majority of countries (11), it was unclear what economic approach is taken, if any. Of the 8 countries that state that economics are considered:
  - 5 countries consider more than 1 economic approach depending on the type of technology, available evidence, and company pricing strategy. For instance, TLV in Sweden requires company submissions, so it is up to the company to choose the most appropriate economic approach, which is then evaluated by TLV.
  - 5 countries adopt a healthcare system perspective in the evaluation, whereas 3 adopt a societal perspective.
- HTA outcomes were considered to focus mainly on identifying appropriate pricing for the technology (1 country), providing information to help decision-makers decide whether access to the technology should be granted (9 countries), or making a reimbursement decision (3 countries).
  - 4 countries had HTA authorities that state that the outcome of the HTA (e.g., the information, advice or recommendations given) is not binding. NICE is the only HTA authority that states that its HTA outcomes can be legally binding in some circumstances but not in others.[20] For example, medical technologies assessed via the NICE technology appraisal programme have legally binding recommendations, but technologies assessed via other NICE HTA programmes, such as the Medical Technology Evaluation Programme or Diagnostics Assessment Programme, do not have legally binding recommendations.[19,20] For the remaining 14 HTA authorities, it was unclear whether the outcome of the HTA was legally binding.

Table 1. Summary of HTA Processes and Requirements for 19 Countries

HTA process	Company submission	Unpublished/ confidential info allowed	Economic approach	Economic perspective	HTA outcomes
26% dedicated 47% general 11% both 16% unclear	53% yes 21% no 26% unclear	26% yes 16% no 58% unclear	42% CUA 16% CEA 16% CMA 11% BIA 58% unclear Some authorities use more than one economic approach	26% healthcare system 16% societal 58% unclear	5% pricing 47% access 16% reimbursement 32% unclear

BIA = budget-impact analysis; CEA = cost-effectiveness analysis; CMA = cost-minimisation analysis; CUA = cost-utility analysis; dedicated = HTA process specific to nonpharmaceutical medical technologies; general = HTA process for any type of health technology.

CONCLUSIONS

- **There are important differences in HTA processes for medical technologies across the world.**
- **Variations in the evaluation process and differing requirements for clinical and economic evidence mean that medical technology companies should plan their market access strategies and the associated evidence needs proactively and based on an understanding of global requirements.**
- **The medical technologies space is rapidly changing, and although some HTA organisations do not have a process (or no specific process) currently, it does not mean one will not be introduced. Therefore, companies need to monitor requirements and adapt plans accordingly.**

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