VALUE IN HEALTH REGIONAL ISSUES 18 (2019) 145–150

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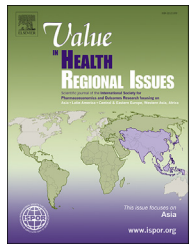

Themed Section: Drug Policies in Asia

Health Technology Assessment and Its Use in Drug Policy in Malaysia

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ABSTRACT

Objective: To describe the process and role of health technology assessment (HTA) in the context of drug policy in Malaysia. **Methods:** We summarized the HTA process through review of documents and reports available in the public domain combined with the authors' experience. **Results:** Health technology assessment plays an integral part in prioritizing treatment in public health facilities in Malaysia, particularly for the Ministry of Health Medicines Formulary (MOHMF). The MOHMF is the reference list of drugs allowed to be prescribed in the Ministry of Health (MOH) facilities. There are 2 organizations within the MOH that conduct HTA as their core activities, namely the Malaysian Health Technology Assessment Section and the Formulary Management Branch of Pharmacy Practice & Development Division. The assessment of pharmaceuticals for the purpose of listing medicines into the MOHMF is under the purview of the Formulary Management Branch. The evidence-based assessment focuses on safety, efficacy, effectiveness, and budget impact of the drug. Cost-effectiveness evidence is currently not mandatory but is of interest to the decision makers. The assessment outcomes are considered by the MOH Medicines List Review Panel for formulary decisions. **Conclusions:** Health technology assessment has supported formulary decisions in MOH. Evidence generation needs to progress beyond efficacy or effectiveness, safety, and budget impact to incorporate cost-effectiveness. Nevertheless, there are challenges to be met to achieve this. The impact of the HTA process is currently unknown and is yet to be evaluated formally.

Keywords: drug pricing, formulary listing, health technology assessment, Malaysia

Introduction

The Malaysian healthcare system is organized into a 2-tier health system: public universal healthcare for its citizens and a private healthcare system. The public system is funded by the government through general taxation revenue with the Ministry of Health (MOH) being the main provider of healthcare services in the country.[1]

Malaysia's national spending on healthcare has doubled during the last 20 years and is expected to continue rising alongside the longevity and affluence of its population. Currently, the public health sector accounts for 52% of the total healthcare expenditure in Malaysia.[2] The Malaysian government has allocated 10% of its national budget to healthcare in 2017, a level on par with many Western countries,[3] although it is still below the World Health Organization's recommended 5% of a country's income.[4]

Pharmaceuticals are responsible for a large proportion of total healthcare expenditures. The sector has grown by an average annual rate of 8% over the last decade, reaching MYR8.6 billion or 16.5% of total healthcare expenditures in 2016. Imported medicines at MYR5.4 billion still account for the largest part of the MYR8.6 billion pharmaceutical market, while exports are only MYR0.7 billion. Generic medicines now account for 55% of the controlled (prescription) medicines market by value.[5]

In the MOH, medicine expenditures have been increasing from MYR1.61 billion in 2010 to 2.38 billion in 2014,[6] accounting for approximately 11.6% of the MOH operating budget in 2014.[7] The increase coupled with rapid diffusion of health technologies has become a challenge for the MOH in continuing to provide access to quality and affordable treatment within the limited budget allocation. Health technology assessment (HTA) is a systematic evaluation of the properties and effect of health

The authors have indicated that they have no conflicts of interest with regard to the content of this article.

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2212-1099/$36.00 - see front matter © 2019 ISPOR–The professional society for health economics and outcomes research. Published by Elsevier Inc.

https://doi.org/10.1016/j.vhri.2019.03.003

technology. Health technology assessment is playing an increasingly important role in informing the relative value and determining how best to allocate finite healthcare resources to ensure long-term sustainability of the healthcare system. Within the last 3 decades, many Asian countries have established their HTA program for various purposes with a different programmatic mix. In this article, an overview of the HTA process in the Malaysia MOH and its role in the decision making for the MOH Medicines Formulary (MOHMF) is illustrated.

Background to Drug Policies

Market Authorization

Drugs must first receive marketing authorization before being offered to the consumers. Marketing authorization or registration of a drug is granted by the Drug Control Authority, which is a body under the administration of the National Pharmaceutical Regulatory Agency.[8] Submission for registration of new drug products, biologics, and generics that contain scheduled poison will be fully evaluated in accordance with either Association of Southeast Asian Nations Common Technical Dossier/Requirements or the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use guidelines. Full evaluation takes 245 working days for new drug products and biologics and 210 working days for generics that contain scheduled poison.

Reimbursement and Pricing

Reimbursement

Upon receiving marketing authorization, the use of a drug in the MOH facilities needs to be preceded by listing the drug in the MOHMF. All drugs administered in public healthcare settings are covered by the MOH. Nevertheless, drugs prescribed and administered in the private healthcare system usually are paid out of pocket or through private health insurance plan.

Pricing in MOH

Malaysia applies a free-market economy and a price deregulation system whereby drug prices in the market are not controlled by the government.[9] In 2014, the Ministry of Finance exempted all drugs under the National Essential Medicines List from taxation as one of the measures to ensure affordability of drugs.[10] Despite the free-pricing system, the drug prices in public facilities are indirectly controlled through the procurement process according to the guidelines and directives of the Ministry of Finance. The principal policies of the government procurement stress the involvement of local industries in such a way that promotes price competition between suppliers and hence procures products with the best value for the money.[11] Similarly, the Malaysian National Medicines Policy has also stated in its generic medicines policy that priority shall be given to locally manufactured medicines during selection for procurement[12]; this promotes affordability because it is found that most of the innovator drugs are 27% to 90% more expensive than generic drugs.[13]

There are 3 methods of drug procurement in the MOH. The first 2 are through concessionaire and central contract at the national level. The concessionaire supplies drugs that are listed under the Approved Product Purchase List (APPL) whereas central contract covers drugs not listed in the APPL and applies to drugs with a procurement value more than MYR500 000 ($122 640).[5] The proportion of medicines procured through concessionaire and central contract were 36.7% and 43.5%, respectively, in 2016.[14] These 2 methods have a similar pricing process that occurs every 2 to 3 years.[15] Throughout the procurement process, pricing activities are involved in the following order: (1) price estimation along with drug specification preparation just before advertisement of tender, (2) price and technical evaluation during evaluation of bidders, and (3) price negotiation when necessary.

Price estimation is a benchmarking process where the MOH conducts a price market survey based on internal or external price referencing. Internal references are drugs that are currently listed in the MOHMF and belong to the same therapeutic group. Both local (such as university hospitals) and international (such as International Reference Pricing[16]) sources are used as external references. Price evaluation occurs after the closing of tender bidding. It is an independent process from the technical evaluation, which evaluates whether a drug fulfills the required specification. The pricing committee uses the most recent internal referenced price and the benchmark price determined earlier to compare against prices that are offered by the bidders. Based on the outcome of the price evaluation, the need for price negotiation will be suggested to the MOH Procurement Board.

The final price for essential drugs should be ideally not more than 3 times the International Reference Pricing.[17] Price negotiation supersedes price evaluation when only a single supplier exists for that particular drug, which usually has no therapeutic equivalents, or for high budget impact drugs that are newly approved for listing in MOHMF. The final price for such is required to be valid for 2 years from the time of listing.[18] The economic evidence from the HTA is rarely considered during drug pricing negotiation because local economic evidence is currently not mandatory and hence not commonly submitted.[18] Nevertheless, other information and evidence from the HTA are referred to during price negotiations of drugs newly approved for listing into MOHMF. The third procurement method is local purchase at the individual institutional level for medicines that are not listed under APPL and central contract, where the value of procurement is less than MYR500 000.[5]

HTA: Current Status

Organizations Involved in HTA

The institutionalization of HTA in Malaysia is driven by the need for evidence-informed policy decision making in the public sector. There are 2 organizations within the MOH that conduct HTA as their core business, namely the Malaysian Health Technology Assessment Section (MaHTAS) of the Medical Development Division, which is designated as the HTA agency of Malaysia, and the Formulary Management Branch of Pharmacy Practice & Development Division (PPDD). Although both organizations advocate evidence-informed healthcare decision making, the scope of activities and purpose of the HTA differ.

MaHTAS: Role & Activities

The MaHTAS was established in August 1995 under the Medical Programme of the MOH to ensure safe, effective, and cost-effective technologies including pharmaceuticals, devices, and procedures are used in the MOH facilities. This is achieved through the conduct of full HTA, mini-HTA (technology review), or rapid assessment (information brief). Its scope has also expanded to develop evidence-based clinical practice guidelines in 2001 and, most recently, horizon scanning of emerging technologies.[19]

The MaHTAS receives requests for full HTA from stakeholders within the MOH. The assessment process begins after the requested topics undergo a priority setting by the HTA Technical Advisory Committee (HTA-TAC) and approval is obtained from the Health Technology Assessment and Clinical Practice Guidelines (HTA-CPG) Council, which is chaired by the Director General of Health Malaysia.

The assessment is performed through a systematic appraisal of published evidence on clinical, economic, social, ethical, and organizational aspects and when needed is supported by a primary research. An HTA report is drafted and subjected to technical review internally, an external review, and review by HTA-TAC before obtaining final approval from HTA-CPG Council. Once approved, official feedback is given to the requester.[19,20] Requests for mini-HTA are received throughout the year from both internal and external stakeholders. Assessment focuses on efficacy or effectiveness, safety, and cost or financial implications. The HTA-TAC is the approving committee while the HTA-CPG Council endorses their decision. Refer to Appendix Table 1 and Appendix Figures 1 and 2 (found at https://doi.org/10.1016/j.vhri.2019.03.003) for details of HTA products and processes by the MaHTAS.[20,21]

The HTA process in MaHTAS is guided by the Health Technology Assessment Manual 2015.[20] The multidisciplinary team comprising doctors, pharmacists, and scientific officers with skills in evidence-based medicine, epidemiology, and economic evaluation at MaHTAS critically assess and appraise the quality of evidences.[19] Continuous capacity building and training of personnel is a priority at MaHTAS. The strong international networking established by MaHTAS with organizations such as the International Network of Agencies for Health Technology Assessment and Health Technology Assessment International provides resources as well as training opportunities for their staff.[22]

Formulary Management Branch, PPDD: Role & Activities

The PPDD is responsible for assessment of pharmaceuticals for the purpose of listing medicines in the MOHMF. The first MOHMF was published in October 1983 with the aim to ensure safe, effective, and cost-effective medicines are used in MOH facilities.[23] The formulary listing process begins with submission of a dossier by the pharmaceutical company (Fig. 1). The PPDD reviews all evidence submitted by the pharmaceutical company and also conducts an in-house assessment. The MOHMF listing is decided by the MOH Medicines List Review Panel (MOHMLRP), which is chaired by the Director General of Health. The committee includes the Senior Director of Pharmaceutical Services, Deputy Director General of Health (Medical), 8 senior consultants from various clinical disciplines, and 4 pharmacists, all appointed by the Director General of Health. The Formulary Management Branch of the PPDD is the secretariat for this committee and coordinates the process for formulary listing.[24] The drug assessment process in the PPDD has evolved over the years from brief reports to full drug reviews, which are classified as mini-HTA according to the definition by the International Network of Agencies for Health

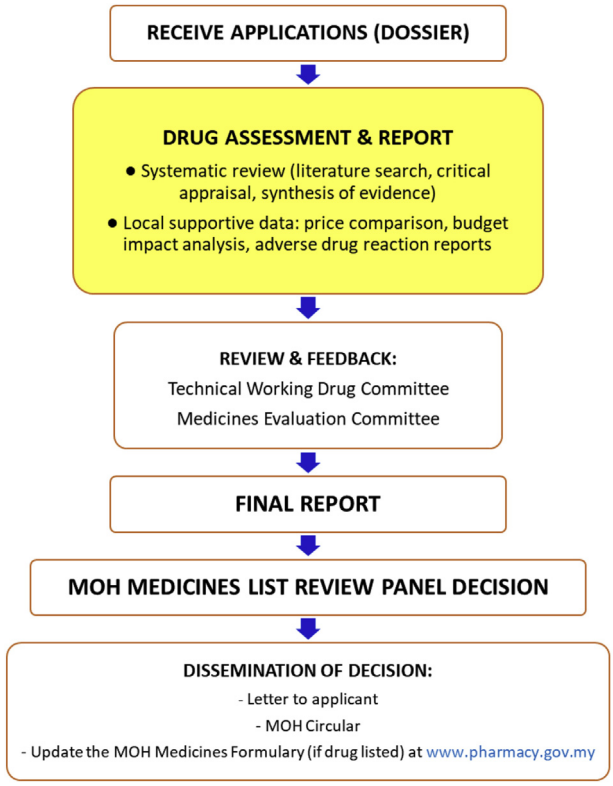

Fig. 1 – Ministry of Health Medicines Formulary listing process for new medicine. MOH indicates Ministry of Health.

Table 2 – Comparison of HTA activities and products between MaHTAS and the PPDD

	MaHTAS	Formulary management branch PPDD
Type of products evaluated	Medical devices, diagnostics & procedures, pharmaceuticals, programs	Pharmaceuticals
Type of HTA products	Rapid assessment Mini-HTA HTA	Mini-HTA Rapid reviews
Purpose of evaluation	Provide evidence-based information for policy decisions of health technologies	Provide evidence-based information for Ministry of Health Medicines Formulary decision
Decision-making committee	HTA-CPG Council: • Chaired by the Director General of Health Malaysia • Committee includes representatives from public, academic, and private sectors	MOH Medicines List Review Panel • Chaired by the Director General of Health Malaysia • Committee consist of MOH representatives
Duration of process	2 weeks—Rapid assessment 2-4 months—mini HTA 8-18 months—HTA	2-3 months
Staff profile	Medical doctor Pharmacist Scientific officer	Pharmacist
Target group/ stakeholders	Public sector Private sector General public Patients	Pharmaceutical company MOH
Accessibility to reports	Full access	Limited to internal stakeholders

CPG indicates Clinical Practice Guidelines; HTA, health technology assessment; MaHTAs, Malaysian Health Technology Assessment Section; MOH, Ministry of Health; PPDD, Pharmacy Practice & Development Division.

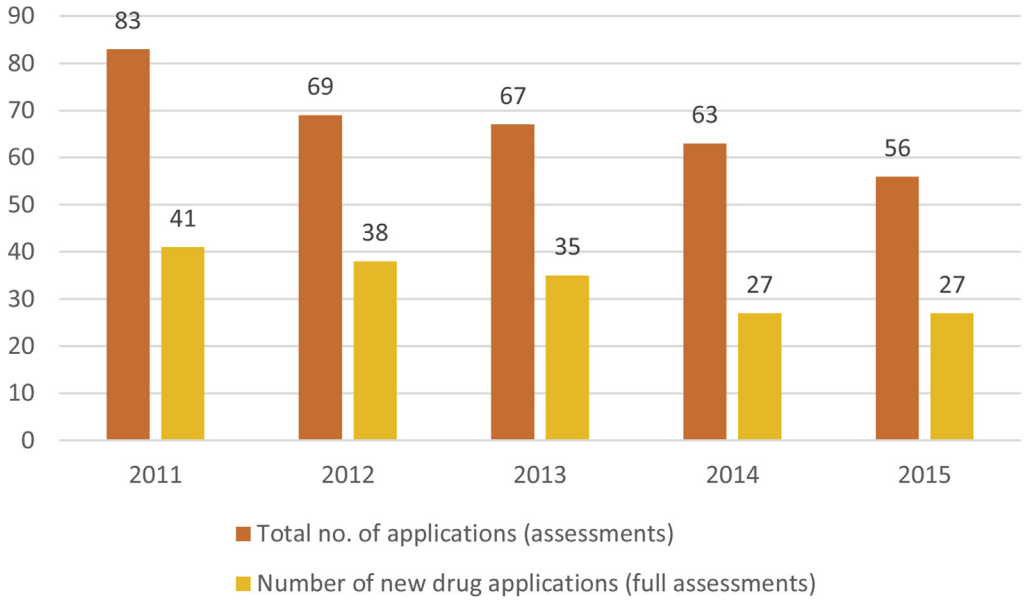

Fig. 2 – Number of drug assessments from 2011 to 2015.

Technology Assessment.[25] Assessments are done for all categories of application (to introduce a new registered drug, add or alter specifications for an existing drug in the MOHMF, and remove listed drugs), either as rapid reviews or mini-HTAs based on category of application.

Unlike MaHTAS, the assessment team in the PPDD consists of only pharmacists but with skills and qualifications in clinical pharmacy, health economics, evidence-based medicine, and health policy. The team undergoes continuous capacity building and training locally and internationally. The PPDD maintains international networking by actively participating in roundtable meetings and conferences related to HTA. The PPDD has published methodological articles in the field of health economics, namely the Pharmacoeconomics Guideline for Malaysia, which was published in March 2012.[26] There are internal guidelines on work process for the drug evaluators and the Submission Guidelines for Dossier to guide submissions for MOH formulary listing.[18] Table 2 outlines the differences between MaHTAS and Formulary Management Branch of the PPDD.

Use of HTA in Formulary Decision Making

The MOHMF is an important document for stakeholders in the MOH since access to treatment is dependent on what is in the formulary. It is used as reference at all levels within the MOH. Therefore, the assessments done by the PPDD, which are used by the MOHMLRP for formulary decision, play a vital role in access to treatment for patients in the MOH.

There is no prioritization of topics for assessment. It is a preset criteria that assessment (mini-HTA) will be done for new drugs as well as for the addition of indications for existing drug. The PPDD performs assessment through a comprehensive literature search

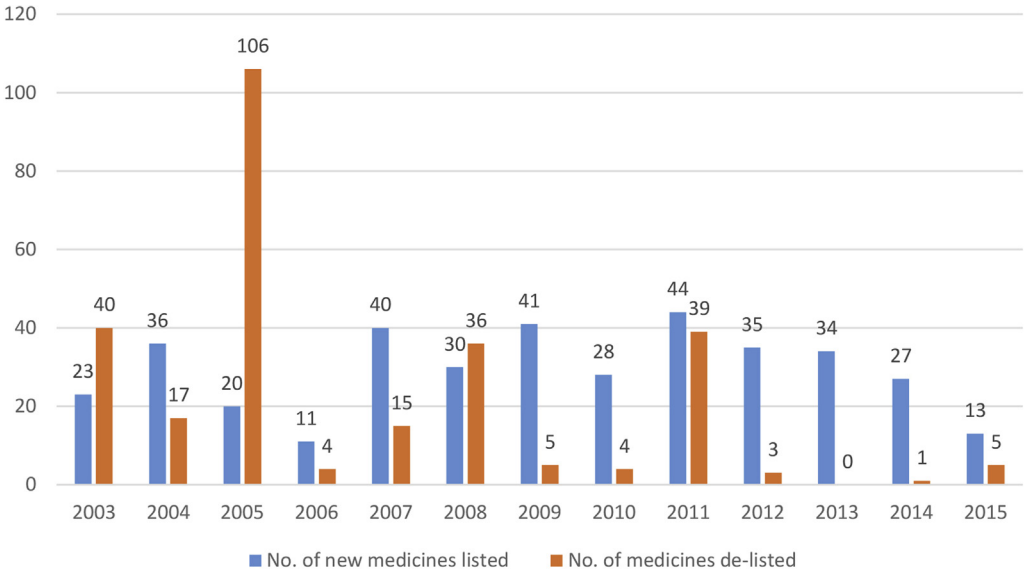

Fig. 3 – Ministry of Health Medicines Formulary Decisions (2003-2015).

and systematic appraisal of published evidence on safety, efficacy, effectiveness, and budget impact. On average, about 60 drugs are assessed annually, of which approximately 50% are full assessments (mini-HTA) (Fig. 2). In view of limited human resources and stringent timelines for the assessment, the PPDD's assessments are restricted to secondary research. The Drug Evaluation Committee and the Therapeutic & Drug Working Committees of relevant clinical disciplines will first provide feedback on the assessment report. The final assessment outcomes and recommendation are presented to the MOHMLRP. The panel deliberates on the findings of the assessment and a decision is made by consensus. There are 3 categories of decision: approved (with or without restriction), rejected, or deferred. A deferred application will be presented in the next upcoming meeting after addressing concerns raised by the panel. The focus on further evidence gathering to tackle the concerns raised for these drugs prior to decision making is indicative of the panel's stand on evidence-based decision making, which is fundamental in the HTA process. Furthermore, the requirement to present the additional evidence in the next panel meeting also minimizes delays in access to treatment. The decisions made by the panel are final with no appeal allowed for rejections. Nevertheless, the pharmaceutical company is allowed to resubmit the application provided the reasons for rejections are addressed. As a result of the HTA process, over the years, many new drugs have been listed in the MOHMF and existing drugs delisted as shown in Figure 3.[6,27,28] Current practice does not cater to routine review of the existing formulary as a whole, but formulary review based on selected drug classes has been initiated recently. Nevertheless, delisting of drugs used as comparators in an assessment does occur which relates to small numbers delisted annually. Rarely, applications are received to delist a drug.

The global trend reflects movement toward use of economic evaluations as part of the evidence-based decisions. Given the complex nature of this evaluation, resource limitations, and absence of country threshold, cost-effectiveness is not a formal decision criterion for MOH formulary decisions. Instead, budget impact is used as a criterion. Nevertheless, the panel has expectations for cost-effectiveness evidence from the local setting to be produced in near future. Evidence generation aligned to stakeholder expectations is important for effective and appropriate use of HTA. Therefore, efforts to generate value-for-money information is important, and how this will be done is still under discussion at the PPDD.

Although the PPDD only assessed pharmaceuticals, MaHTAS assesses all medical technologies. Although there seems to be an overlap of assessments for pharmaceuticals between the 2 agencies, MaHTAS HTA conclusions and recommendations are not binding nor linked to formulary listing in the MOH. Moreover, the number of pharmaceutical assessments by MaHTAS are limited with more assessments done for other medical technologies (Appendix Table 3, Appendix Figs. 3 and 4, found at https://doi.org/10.1016/j.vhri.2019.03.003).[22]

Challenges

There are methodological and process standards recommended for the conduct of HTA.[29] Being the national HTA agency, MaHTAS has over the years incorporated most of these recommendations in conducting HTA. Despite many years of evaluating drugs for formulary listing process, the PPDD is still catching up to progress beyond their rapid assessments of drugs. Since MOHMF has a significant impact on access to medicine, stakeholders expect timely assessments and formulary decisions. There are 3 MOHMLRP meetings annually at intervals of 4 months. As the HTA has to be timely, the 3-month duration available to conduct assessments for an average of 20 drugs prior to each meeting becomes a major limitation for the PPDD to conduct full HTA as well as primary research to support the HTA activities. In addition, there is limited capacity in human resources. Nevertheless, the PPDD is constantly improving the work process to achieve standards set for conduct of HTA.

Health technology assessment is arguably a data-intensive and specialized field. Ensuring a culture of using evidence for decision making in policy choices, combined with access to local data, especially for cost and resources, are considered to be key aspects for a health system to conduct and use HTA effectively and appropriately. Lack of access to quality and credible local epidemiology, cost, and utility evidence could severely hinder generation of informed assessment. Currently, this is a critical challenge being faced by both the PPDD and MaHTAS. The country's public health service has a well-developed infrastructure of hospitals, a partially developed electronic medical record systems, and a number of disease registries. Nevertheless, access and dissemination of studies from most of the government data sources are controlled and vary according to the organization that manages the database. Furthermore, there is an absence of cost estimates for procedures/conditions and lack of utility estimates and agreed threshold for cost-effectiveness, which is challenging for the HTA process. The available published EQ-5D tariff were based on a nonrepresentative sample of the population[30] and the threshold used by local researchers was set arbitrarily.[31,32] These factors are also a concern for other stakeholders including the pharmaceutical companies. Lack of access to local data poses a challenge for the conduct of local economic evaluation. Taking this limitation into consideration, submission of local economic evaluation has not been made mandatory yet by the PPDD for the application of formulary listing. Nevertheless, research on quality of life, resource use, and clinical outcomes in the local setting is being encouraged to provide supporting data for local economic evaluations.

Apart from reliable information, the existence of policy and procedures within the system that promote systematic use of HTA in decision making is also important. This needs to be strengthened to ensure transparency and legitimacy of the decision process in the local context.

Conclusion

The HTA process for formulary listing is undergoing progressive changes. The stakeholders involved support the HTA process. Nevertheless, meeting stakeholder expectations is a key challenge, particularly in providing local cost-effectiveness data. To overcome this issue, one potential avenue is to have internal collaboration between the PPDD and MaHTAS and tap into resources in academia to optimize resources in drug assessments. Additionally, though a standardized HTA process exists for formulary decisions, its impact on formulary decisions is yet to be evaluated formally.

Acknowledgments

We thank the Director General of Health Malaysia for his permission to publish this article.

The authors have no other financial relationships to disclose.

Supplemental Materials

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.vhri.2019.03.003.

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