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Pharmaceutical companies' views on a health technology assessment (HTA) entity in Saudi Arabia

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ABSTRACT

Saudi Arabia is undergoing a massive healthcare transformation to fulfill its new, national "Vision 2030." To align with this objective, Saudi Arabia is establishing a new, independent and evidence-based health technology assessment (HTA) entity to help it maximize health gains through efficient use of resources. This study was designed to ascertain how pharmaceutical companies perceive the creation of such a national HTA entity in Saudi Arabia; what they think about it and expect from it. To achieve the study's aim, we held a workshop in Riyadh, Saudi Arabia, lasting four and a half hours and hosted by the Saudi Ministry of Health (MOH). We invited 16 market access directors and managers from different multinational pharmaceutical companies to discuss the establishment of a national HTA entity. The findings from the workshop were structured around three axes: vision and remit; HTA method; and implementation and practical considerations. Overall, the pharmaceutical company participants were positive about HTA's value for the Saudi healthcare system and expressed willingness to adapt to meet its future requirements.

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1. Introduction

During the last decades, several governments have been faced by the challenge of controlling the escalating healthcare costs and expenditure, partly as a consequence of aging and increasing populations, the growing burden of chronic diseases, and the rapid diffusion of new technologies, some associated with limited benefits at unjustifiably high prices (Drummond et al., 2009; Gronde et al., 2017). Although the introduction of new technologies into healthcare systems has been perceived as a significant cost driver,

new mechanisms for procuring innovation and more nuanced views on value are generating the hope that important qualitative improvements need not come at the expense of fiscal sustainability. With optimal processes, healthcare systems and the populations they serve can reap the rewards of new technologies and innovations while maintaining value for money. One of the mechanisms being introduced is health technology assessment (HTA), which has already been adopted in several countries including the United Kingdom, France, Germany, Canada, and Sweden. HTA is described by the European network for Health Technology Assessment (EUnetHTA) as "a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value. Despite its policy goals, HTA must always be firmly rooted in research and the scientific method" (EUnetHTA, 2007). It functions to enlighten reimbursement agencies, payers, decision-makers, and others who are responsible for healthcare funding, planning, purchasing, and investment. HTA can increase value for money by shifting resources from

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inaccessible or cost-ineffective technologies or those with relatively inferior clinical benefit (Hutton et al., 2008).

Pharmaceutical companies recognize the importance of adopting HTA as it will enable assessment of medications based on the full spectrum of associated costs and benefits rather than just acquisition costs, in addition to encouraging innovation (EFPIA, 2005; Fibig, 2013; Sorenson et al., 2008; Wilsdon et al., 2014), although there is the risk that such cost-driven assessment might clash with these organizations' primary aims. For instance, there are increasing concerns about whether HTA processes may slow down decision-making or delay patients' access to new medications (Fibig, 2013; Lothgren and Ratcliffe, 2004). The 2018 EFPIA survey found significant variance in access to new medicines across Europe: in some countries it took seven times longer to get access to new medicine than in others. This had a knock-on effect on how quickly patients got access to new treatments; typically, in Northern and Western Europe it was 100 to 200 days after market authorization by European Medicines Agency (EMA) was granted, while patients mainly in Southern and Eastern Europe had to wait 600–1000 days. Furthermore, the survey found that cancer treatment reimbursement across 29 European countries took an average of 445 days; Germany was the fastest, at 119 days, while the longest was Serbia, taking over 900 days (EFPIA 2018). Moreover, Akehurst et al., studied the period between market authorization and HTA decision; they found likely factors causing delay to stem from HTA bodies having different processes, giving different weight to various information sources, and prioritizing certain criteria, such as disease severity and drug efficacy, over others, such as cost-effectiveness (Akehurst et al., 2017).

HTA reviews vary significantly in scope, relevance, and implications for pharmaceutical companies (Lothgren and Ratcliffe 2004). Ultimately, the burden of proof of medications' value for money lies with the manufacturers, who are required to submit a comprehensive dossier to the HTA body, containing evidence and information on each medication's clinical effectiveness, safety, quality, budget impact, and cost-effectiveness, although these requirements might differ from one country to another. These dossiers are based on real-world naturalistic studies balanced against local standard of care and current clinical practice (Luce et al., 2010; van Nooten et al., 2012); this is as opposed to marketing authorization requirements, where the focus is solely on the treatment's risk-benefit profile compared to a placebo in a rigorously controlled environment, typically a randomized controlled trial, with particular attention paid to internal validity, safety, efficacy, and quality of manufacturing (Lothgren and Ratcliffe, 2004; Panteli et al., 2015). To perform its tasks, an HTA body needs to assess evidence of varying types and quality levels for each medication (Hutton et al., 2006). It may then conduct additional analyses to try to verify the assumptions made in the manufacturer's dossier and generate additional evidence, before deciding whether to reimburse, to reimburse under certain conditions, or not to reimburse the medication under review. This decision can be binding or non-binding for healthcare services providers and payers based on HTA mandates and remits, which can differ from one country to another (Akehurst et al., 2017). This process can be harder and take longer if the HTA body has insufficient resources to deal with the number of manufacturer applications submitted.

Currently, Saudi Arabia is in the final stage of establishing a centralized, independent, and evidence-based HTA entity to help it maximize health gains through efficient use of resources. Introducing HTA in Saudi Arabia will support better outcomes through the delivery of innovative, value-based population health by providing evidence-based guidance on the value-based price that should be paid for health technologies, streamlining and accelerating the decision-making process for clusters (consisting of a number of hospitals and primary healthcare centers), diminishing

the administrative burden, supporting pricing and reimbursement decision-making, informing clinical guidelines developed by the Saudi Ministry of Health (MOH), and strengthening Saudi Arabia's place as a leader in the Gulf Cooperation Council (GCC) region and across the globe in addressing complex issues related to health technologies reimbursement and supporting evidence-informed health-policy and decision-making (Al-Omar et al., 2019). As a result of this, pharmaceutical companies in Saudi Arabia will be directly affected by the HTA entity and will become key stakeholders in the designing of a national HTA strategy. Up to date, there are no local studies investigating pharmaceutical companies' views on HTA in Saudi Arabia, so this study aims to explore that.

2. Methods

We carried out qualitative research to capture and generate an in-depth understanding of participants' views and experiences on the topic under investigation. The team held a four-and-a-half-hour workshop in Riyadh, Saudi Arabia (29 January 2019), physically hosted by the MOH. We invited 16 participants using purposeful sampling from a variety of multinational pharmaceutical companies. The invited participants included market access directors and managers who are responsible for the Saudi pharmaceutical market and based in Saudi Arabia or GCC or Middle East and North Africa (MENA) regions. The rationale behind inviting representatives from the market access department is that this department is involved directly in the process of pricing and reimbursement, marketing authorization, and launch of pharmaceutical products. In addition, market access directors and managers have extensive knowledge and understanding of global HTA agencies, since they deal with them, their assessment requirements and dossier submissions, on a daily basis. The workshop focused on the establishment of a centralized Saudi HTA and pharmaceutical companies' views on its vision, remit, method, and implementation.

The workshop was part of a wider project undertaken by the Saudi MOH for developing and establishing an HTA strategy and entity as part of the National Transformation Program (NTP). A stakeholder workshop was chosen to collect the qualitative research data due to its consultative and explicit nature. It was designed to be interactive and engaging, to encourage the participants to focus on the specific issues in more depth than would be possible in a standard, more controlled focus group discussion with only around 6–10 participants. Stakeholder workshops usually comprise more than 10 multi-level participants and are used to explore various visions and objectives creatively and to produce key outputs and decisions relative to upcoming research (Ahmed and Asraf, 2018; Brugha and Varvasovszky, 2000; Caretta and Vacchelli, 2015; Ekirapa-Kiracho et al., 2017; Ørngreen and Levinsen, 2017).

All participants received a brief agenda in advance of the workshop, which began with the participants briefly introducing themselves, giving an overview of their qualifications and job roles, followed by a structured presentation overseen by the MOH-HTA core team and facilitated by the management consultancy team and international subject matter experts (SMEs). The presentation introduced the Saudi healthcare market and system, the challenges and opportunities for better resource optimization, and the role and functions of HTA agencies worldwide. After the presentation, most of the time was dedicated to plenary discussion. No handouts were distributed during the workshop, to prevent the risk of potentially sensitive information about Saudi Arabia's plans for an HTA entity leaving the room and to ensure that the conversation flowed as freely and openly as possible, without leading its direction in

any way. The following general questions were asked to spark the discussion:

1. What is the expected vision and remit for the Saudi HTA entity?
2. What HTA method will it adopt?
3. What practical issues need to be considered during setup and implementation of the Saudi HTA entity?

The workshop was digitally recorded for verbatim transcribing. Two MOH–HTA core team members, working independently, analyzed the transcripts thematically using Braun and Clarke's six-step approach (Braun and Clarke, 2006). They then discussed the generated key themes and subthemes they had identified, along with those listed on the whiteboard during the workshop and validated by industry representatives, in order to harmonize them. NVivo® for Windows® Version 11 (QSR International; released in 2016) was used to facilitate the coding and sorting of the transcripts. None of the perspectives generated were considered representative of any pharmaceutical company's official position.

3. Results

The workshop findings were structured around three major themes and eleven subthemes relative to HTA strategy and implementation in Saudi Arabia (see Table 1).

3.1. Vision and remit

The pharmaceutical company participants listened to the proposed HTA strategy and understood, overall, that the main value

of a centralized HTA function would be to provide clear guidance on the appropriate use of technologies across the health system, thereby limiting the need to have multiple negotiations with stakeholders at each step of the pricing and reimbursement chain. The majority of participants inquired as to how HTA would fit into the decision-making process, for example, if products undergoing HTA would subsequently be tendered by the National Unified Procurement Company (NUPCO). They also flagged the potential for HTA to introduce further delays in patient access to new health technologies, but agreed that this could be mitigated by parallel consultation with the Saudi Food and Drug Authority (SFDA) and appropriate HTA processes.

More specifically, the pharmaceutical company representatives understood that Saudi Arabia's ambition was to be innovative and to lead the way with HTA in the region, and confirmed that—as the biggest market in the GCC—it was well suited to do so. Accordingly, they highlighted the importance of the HTA strategy and method being fit for purpose in Saudi Arabia, notably by being culturally appropriate and reflecting the country's preoccupations, systems, and workforce. They also noted the importance of learning not just from HTA bodies that have been in place for many years but also from more recently established ones whose successes and failures can provide good insights for Saudi Arabia's emerging HTA capability.

Given the numerous choices surrounding mechanisms for managing the pricing and reimbursement of health innovation, several participants did raise the question of whether HTA is the optimal tool to promote value-based pricing. They highlighted the challenges around current delays associated with the use of external reference pricing (ERP), which has an impact on launch

Table 1
Supporting quotes from workshop participants.

Theme	Subtheme	Supporting quote
Vision and Remit	Value of HTA	"HTA not only adds value to the system and aids decision making, but it also provides a solid basis for evidence-based care." Participant 2
	Fit for Purpose	"HTA can be really useful for making reimbursement decisions." Participant 7
		"As long as HTA is culturally appropriate, then it will be fit for purpose." Participant 5
	Mechanism	"We need to make sure that any HTA we setup is culturally appropriate for our country." Participant 2
		"It's good to look at other HTA models, but, in the end, we need to focus on what is right for us, not other countries." Participant 9
		"If HTA's decisions are final, and cannot be challenged elsewhere in the system, then it's a good tool." Participant 8
	Efficient Approach	"For each technology, it needs to reach a fair price that takes into account the healthcare system that technology is being built to serve. We have such a burden of disease in Saudi Arabia that it would be wonderful to get innovative products into our hospitals and clinics as soon as they have been granted FDA or EMA approval. If HTA could achieve that, it would be great." Participant 2
		"HTA vision should focus on patients' access and equity regardless the entity design." Participant 12
		"It's likely that HTA will attract multinational companies because they will have incentive to be innovative especially when it is linked to patients' access after assessment." Participant 1
		"Considering how fragmented the healthcare sector is right now. The whole country is undergoing a huge transformation, which will likely take a few more years at least, so how would HTA fit into any changes to the setup of the government? Will it stay under the umbrella of the MOH or are we going to have a national HTA that covers all the sectors under the government, overseeing access decisions, pricing levels, and reimbursement?" Participant 6
	Remit	"It is important to understand how HTA decisions feed into the tender and procurement processes to avoid any kind of difficulties in the future." Participant 14
"How will decisions be made and how transparent will they be, This is really important for us as multinational companies." Participant 7		
Choice and Feasibility	"I think that, first; we need to define the direction want to go in, because clinical challenges in methodology are different from economic ones." Participant 1	
	"The immediate economic challenge is that we don't have sufficient local data available to create an economic model. For instance, national cost data, the size of the eligible patient population" Participant 10	
HTA Method	Definitions	"It is critical that we define what 'high impact' means within the Saudi context—will it be the disease burden, the impact on patients, the financial impact, the health system's priorities? These are all relevant areas." Participant 4
	Data	"We have a mix of data and data problems. Some data was collected by institutions, but it focuses only on particular initiatives or specific diseases. Then you have the issue of accessibility—who can access it or mine it to extract certain variables out of it. More robust data management tools are available, but we have a long way to go." Participant 9
Implementation and Practical Considerations	Transition Phase	"We would need a transition phase, perhaps in the form of an initiative, where companies can submit for assessment." Participant 4
	Collaboration	"HTA definitely needs to work in parallel with SFDA for advance assessments and to speed up the process. Streamlined collaboration needs to happen to ensure faster patient access to medications." Participant 11

sequencing in Saudi Arabia and other countries. In addition, they raised concerns about the impact of HTA on global price referencing should HTA prices subsequently be used by the SFDA to set its own prices. They also flagged issues to do with the tendering that would continue to occur post-HTA, which would lead to further decreases in prices that are not connected to the value provided by new health technologies.

Several participants suggested that reviews of HTAs conducted by other bodies such as the National Institute for Health and Care Excellence (NICE) in England and Haute Autorité de Santé (HAS) in France could be useful in constituting an efficient approach to limit the delays to patient access that may ensue from HTA if not conducted properly. In line with some of the HTA reviews already conducted by various committees and institutions, for example the Saudi Health Council (SHC), they also emphasized the importance of having innovative payment models and agreements that working hand in hand with HTA, including but not limited to managed entry agreements (MEAs) and value-based payment.

In line with local health experts and institutions consulted in similar workshops (Al-Omar et al., 2019), the majority of participants agreed that the HTA entity would need to have a strong, clear and far-ranging remit in order to be relevant. The current fragmentation of the health system together with the need to negotiate pricing and coverage with a large number of hospitals and stakeholders were often mentioned as issues—highlighting the need for HTA to extend beyond the current population covered by the MOH, in order to streamline discussions and accelerate patient access. This was also expected to reduce disparities and multiple price cuts associated with the existence of national and local hospital formularies.

All participants were familiar with the impact of HTA in other geographies, and therefore wanted to ensure that the impact of HTA on patients and innovators would be well understood. In order to accomplish this, they requested more clarity on the processes, methodology, and outcomes of the proposed HTA entity—including how HTA would fit into the current pricing and reimbursement flow, and whether it would affect price, reimbursement, and/or coverage at both national and local levels. They noted the importance of having visibility of the HTA entity's timelines, and of understanding how many technologies would be covered each year and which technologies would likely be selected, in order to adjust their efforts accordingly.

3.2. HTA method

The proposed method to be used for HTA was the principal topic of discussion during the workshop. The majority of the participants acknowledged that the choice and feasibility of individual methods—for example, clinical value scales and cost-effectiveness modeling—would be dependent on both capabilities and data availability. They mentioned the importance of using data and assumptions relevant to the Saudi situation when deciding matters including, but not limited to, standard of care, treatment pathways, and costs, while recognizing the need to make do with alternatives as the data infrastructure is strengthened. Should cost-effectiveness be the method of choice, they indicated the need to set up the right, unified willingness-to-pay (WTP) for the country, and raised concerns about whether this would be possible given the differences across hospitals and clusters. Overall, they agreed that the method should apply uniformly to all hospitals and health settings to ensure equality of access.

All participants were keen to obtain clear guidance on and definitions of what would constitute value and innovation for the Saudi HTA. They requested a broad definition of value, incorporating not only clinical factors but also burden of disease, end-of-life considerations, and wider societal benefits, such as impact on care-

givers, as relevant to the Saudi culture. However, they acknowledged that this would be limited by the poor availability of data and the lack of standardization across clinical settings of care. They also reported that there was a tension between value and budget impact, and that HTA recommendations should be fully decoupled from affordability concerns.

Data was an important preoccupation for all participants, a source of both concerns and optimism. They said that more data is available in Saudi Arabia than is typically acknowledged, but that access restrictions, uneven capabilities and quality of institutional data, and lack of willingness to share are the main barriers to making the most of it. Further, beyond the lack of clinical trials conducted in Saudi Arabia, they noted the existence of health data across several large hospitals and clusters that should be used as part of HTA. They deemed the use of data from other countries acceptable where transferable, in order to limit the burden of collecting data, especially while the Saudi infrastructure is developed, but agreed that support should be given to obtaining better Saudi data. They were therefore interested to hear about current initiatives, such as the launch of unified electronic health records, to bridge the current gap and provide continuous data input.

3.3. Implementation and practical considerations

The route toward implementation of the HTA vision was deemed to be as important as its intended scope and methodology, particularly in the context of a changing health system. The majority of participants highlighted the need to have a transition phase, which would progress from a “light” to a more “advanced” method. The aim of this transition phase would be to trial the HTA process and give time to invest in the necessary capabilities for both the MOH and industry—it was agreed that all would need to hire new staff, and that companies, in particular, would need to adapt global materials and collect Saudi Arabian data in order to respond to the HTA requirements. The participants also suggested that enrollment in this transition phase should be optional and that participating companies should be rewarded, for example with faster or unilateral access.

Several participants converged on the need for collaboration during and after the setup of the HTA entity and processes. They suggested establishing early scientific advice and parallel consultations with the SFDA to decrease assessment timelines and hasten patient access. They also suggested an interface with NUPCO to avoid introducing multiple rounds of price cuts unrelated to health innovations' value. It was agreed that data should be shared more unilaterally across hospitals and health entities, while protecting patient interests and data privacy. Beyond this, the participants emphasized the need for industry engagement throughout the establishment of the HTA entity, including when defining the methodology and requirements—they reported that this collaboration would be key to ensuring continued innovation and access to the latest medicines in Saudi Arabia.

4. Discussion

Since HTA first appeared three decades ago, the number of HTA bodies has grown dramatically. The proliferation of these bodies is directly linked to societies' wish to get more value for the money they invest in healthcare. The newly established HTA bodies have been charged with assessing the quality, safety, efficacy, and costs of new drugs compared with all other relevant alternative treatments. Only the most innovative and cost-effective new treatments are now considered for reimbursement. The HTA bodies, however, operate very differently from the traditional drug regulators due to differences in mandates and remits. Therefore, pharma-

ceutical companies need to be aware of new health initiatives, to understand and cope with these differences, and to work within the new, evolving structures that are unlike those that have been in place at any time in the recent past.

This paper is one of the first to present pharmaceutical companies' perspectives on and expectations for the upcoming Saudi HTA entity from a strategic position. Overall, pharmaceutical companies participants were positive about HTA as a valuable tool for ensuring the sustainability of health systems, stimulating innovation, bringing more transparency to systems, functioning as a means for making decisions about trade-offs in the healthcare systems, and rationalizing pharmaceutical expenditure. Moreover, the participants considered HTA to be the most appropriate mechanism for informing decisions on medications reimbursement, predicting that it will have a positive impact on patients, the healthcare system, industry, and society overall. The industry representatives agreed that, in addition to aligning with Saudi's Vision 2030 objectives, HTA is emerging in Saudi Arabia as well as in other countries for similar reasons: to improve coverage and healthcare standards, to broaden access to and diffusion of innovation, and to target areas of prevalent diseases where patients' medical needs are currently unmet.

Several expensive and innovative technologies, such as gene and cell therapies, designed to address serious diseases in targeted patient populations represent the future of medicine. These therapies will call for innovative payment models and MEAs sooner than expected (Kleinke and McGee 2015); thus, the Saudi HTA entity would also need to explore new models for financing such therapies. MEAs agreements such as financial-based agreements and outcomes-based agreements are widely used in several countries such as Italy, the UK, and Australia to address uncertainties associated with therapies (Ferrario et al., 2017; Piatkiewicz et al., 2018; Robinson et al., 2018). Subscription, also known as Netflix model, is an example of innovative payment model. To demonstrate subscription model value, a study from Australia, despite providing only limited data, suggested that stakeholders, consumers, payers, and manufacturers might derive net benefits from using Netflix, to market hepatitis C products (Moon and Erickson, 2019). Any of these models and agreements would provide the pharmaceutical industry with incentives for coming up with innovations by compensating for the cost of developing new products. This should have the effect of encouraging pharmaceutical companies to develop higher-value products that address important therapeutic gaps and speed up patient access to breakthrough therapies, thus ensuring the financial sustainability of the healthcare system. However, it is not feasible for a single payment model to guarantee all these benefits at the same time; therefore, a combination of models is needed.

Alongside this, workshop participants from the pharmaceutical industry expressed awareness that establishing a Saudi HTA entity and setting up a new reimbursement chain would result in their having to spend more on new drugs to get them assessed, which might delay patients' access to them. They also believed that the process of getting new medications reimbursed would become more time-consuming and complex process, requiring specific additional resources, particularly in terms of preparing quality dossiers and submitting them in a timely manner as per HTA guidelines. This concern from industry is supported by several studies from different countries. The findings from these studies indicated that HTA may frequently be held accountable for delayed patient access to new drugs (Akehurst et al., 2017; Babar et al., 2019; Salek et al., 2019). However, this delay is multifactorial and it can result from other reasons some rooted in medicines access system itself while others related to pharmaceutical company access strategies as highlighted by one study from Europe (Wilking et al., 2019). For one thing, it was considered that multi-layered

decision-making processes often result in duplication and excess time spent on review processes by different entities (Salek et al., 2019). Another factor making the process more time-consuming and complex, multidisciplinary nature of HTA assessment, particularly where capacity is an issue. The fact that there are no clearly defined timelines within which HTA bodies must make reimbursement decisions was also considered to be a problem. From companies side, failing to align evidence during submission is one of the most prevalent delaying factors; issues reported ranged from defining patient populations and comparing new treatments with current best standard of care or best supportive care in case of lack of intervention, through trial design and having surrogate endpoints that cannot be linked to hard morbidity and/or mortality endpoints, to statistical analysis (Cox and de Pourville, 2015; Henschke et al., 2013; van Nooten et al., 2012). Moreover, the fact that companies tend to focus on the price at registration level, with the aim of achieving the highest possible price by following specific tactics, means that companies often consider certain markets less priority for registration than others because their pricing system is based on ERP, which affects the price. As Kanavos et al. have noted, ERP can lead to launch delays, launch sequencing or failure to launch at all, which in turn leads to late access to specific markets (Kanavos et al., 2020). Further, some companies prefer to wait for the formal HTA bodies in some countries to make their reimbursement decisions before submitting their dossier to other HTA bodies, which can also cause delays, especially where companies fail to submit in a timely manner.

The participants also raised a concern about the operational timelines for the new HTA entity, as it will require industry to invest more in market access departments to hire more staff or relocate existing staff and to train employees on the Saudi HTA entity process and method. In order to ensure optimal implantation of HTA in the country, several challenges need to be overcome, including the lack of available and accessible local epidemiological data and registries, the lack of available national cost data, the need for independency and transparency in decision-making, and the need to design an HTA process and method that are uniquely suited to Saudi Arabia. Despite HTA's extensive and increasing use as a decision-making tool, its processes and methods pose significant challenges. HTA should be grounded in robust and transparent processes and methods that are based on clear, standardized guidelines that outline evidence and methodological requirements. It is also crucial for HTA processes and methods to recognize the unique needs and circumstances of individual countries, particularly for those with limited capacity as pointed by several studies (Nicod et al., 2019; Schwarzer and Siebert, 2009). If the HTA method is not sufficiently robust, it could have a negative effect on patients; they might not get access to treatments if resources are not used to optimal advantage and if the healthcare sector's already insufficient funds are diverted inefficiently elsewhere. Therefore, it is vital that attention is paid to all of these issues during the HTA setup and implementation stages. Our findings from the workshop are in agreement with those of the broader pharmaceutical industry on the complexity of HTA, its methods, and its challenges to optimal implementation, specifically relative to the HTA systems in France, the UK, the Netherlands, Sweden, and Greece, as discussed by Lothgren and Ratcliffe (2004) and Armataki et al. (2014).

Communication and collaboration with major organizations such as regulators and healthcare facilities are necessary, as such organizations can offer significant benefits by strengthening HTA's legitimacy and increasing transparency and acceptance in reimbursement decision-making (Nielsen et al., 2009; Wang et al., 2018). In general, communication and collaboration are not easy because various interests and perspectives must be balanced in a process involving various organizations. Establishing an early com-

munication and collaboration process between the SFDA and the HTA entity could prevent delays both to the review processes and to patients' access to new and effective treatments; it would also minimize the likelihood that work would be duplicated work, and potentially increase the number of positive reimbursement recommendations. This was in line with the findings from a study from Europe which reported that pharmaceutical industries valued and encouraged the continuous communication and collaboration between pharmaceutical regulators and HTA bodies (Balaisyte et al., 2018).

Overall, the method used for the study—gathering industry insights through a workshop—was appropriate for the purpose, inexpensive, and able to provide credible findings within a relatively short period of time. Pharmaceutical industry discussions have the advantage of providing views from a group of knowledgeable and experienced individuals. As such, it is a study design that has been used extensively in healthcare for similar purposes including discussion of policy domain (Al-Omar et al., 2019; Debrand and Dourgnon, 2010; Diaby et al., 2015; Simpson et al., 2008). Multiple measures were used to ensure the trustworthiness of this study, maintaining credibility, transferability, dependability, and confirmability, and thus building the strength of the study as a whole. These measures included inviting market access directors and managers from different multinational companies to maximize the variation of views on HTA, using a predetermined set of questions in addition to probes and prompts to generate further explanation from workshop participants, ensuring the consistency of transcripts by involving two independent team members, and presenting findings by using apt quotations. One limitation of this study was that the participants did not always reach consensus, although we reported any divergence of opinion and highlighted areas where further investigation and discussion would be needed. Another limitation was that the limited number of industry participants potentially meant that not all insights were considered, although a larger number of participants would have made it more difficult to manage the discussions in terms of taking notes and achieving consensus on recommendations. Finally, the opinions collected during the workshop were attributed to specific participants in the field of market access, but they were not quantified either by voting or through the Delphi method, meaning that the strength of opinions could not be ascertained.

5. Conclusions

In summary, we found that pharmaceutical companies recognize the importance of HTA as a mechanism for making decisions about whether or not to pay for technologies (access and coverage) and, if so, how much to pay (reimbursement) in light of the high and growing costs of healthcare, in particular related to pharmaceutical expenditures. Pharmaceutical companies are willing to adapt to meet the future requirements of the Saudi HTA entity for assessing health technologies. However, it should be recognized that many hurdles need to be overcome and there are numerous opportunities that must be taken advantage of. We believe that our findings will help to shape Saudi Arabia's HTA strategy as well as informing the strategies of other countries considering or in the process of introducing HTA as a decision-making mechanism. The findings and conclusions of this study will be taken forward to inform a more robust scientific study.

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Declaration of Competing Interest

The authors declared that there is no conflict of interest.

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