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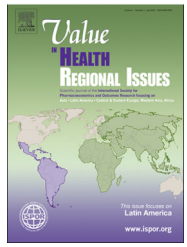

Managed Entry Agreements for Pharmaceutical Products in Middle East and North African countries: Payer and Manufacturer Experience and Outlook

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ABSTRACT

Objectives: The first objective is to describe current managed entry agreement (MEA) activity in the Middle East and North African (MENA) region and the pharmaceutical decision makers' perception and use of these agreements; The second objective is to describe the challenges as well as to reflect on the uncertainty related to MEAs implementation and the future outlook for MEAs activities in the region. **Study Design:** A prospective cross-sectional survey. **Methods:** A questionnaire was sent to several pharmaceutical manufacturers and public officials involved in pricing and reimbursement of pharmaceuticals in the region. **Results:** Of the 62% of total respondents, 25% were from the public sector, with the remainder from the pharmaceutical (pharma) industry. Only 42% of participants reported having MEAs running in their institutions, the majority representing Lebanon. All respondents reported the use of financial-based agreements, most referring to "discounted treatment" and, to a lesser extent, a "price volume agreement." Financial-based agreements were reported as either the only type of MEA (71.4%) being used or as being used with outcomes-based agreements (28.6%). The majority of participants ranked challenges in identifying and measuring relevant data as well as the lack of expertise in assessing health economics data. The majority of respondents projected an increase in the use of MEAs to address budget impact while improving access to innovative care. **Conclusions:** Few MENA countries are implementing MEAs, which could be due to lack of data infrastructure as well as a shortage of experts in health economics. Health care stakeholders continue to be optimistic regarding the potential of MEA implementation.

Keywords: financial-based agreements, health economics, managed entry agreement, MENA, outcome-based agreements, performance-based risk-sharing arrangements.

Background

Globally, over the last decade, there has been enough growing interest in health care systems to introduce managed entry agreements (MEAs) to provide improved access to costly, innovative medicines at a time when governments worldwide have been struggling with health care budget constraints due in part to an aging population with increasing health care demands. To provide patients with more rapid access to these innovative technologies that provide value for money, new reimbursement decisions and tools, such as MEAs, are being adopted [1–3]. An MEA is defined as an arrangement between a manufacturer and payer that enables access to new technologies in health care. These arrangements can exist in a variety of forms, such as outcome–based agreements or financial-based agreements as well as a combination of both agreements. Regardless of the form MEAs take, they all aim to distribute the financial risk of investing in new technologies between the manufacturer and payer, while at the same time addressing uncertainty around these new technologies [1–3].

In recent years, various types of conditional coverage decisions have emerged. By tracking the performance of a product in a given population, manufacturers and payers have been able to facilitate the entrance of new technologies into the market by allowing the basis of reimbursement to be dependent on and determined by outcomes [2].

There are three broad categories characterizing the major forms of MEAs which handle payer-provider arrangements [4–7]. Financial-based agreements, which address cost-sharing efforts, facilitate manufacturer contributions to the cost of a new health drug, product, or technology (e.g., discounts or rebates, price-volume agreements, utilization caps) for a particular patient or population without linking reimbursement to health outcomes [5,7]. These types of arrangements have been implemented globally (i.e., United Kingdon [UK], Italy), and each type has unique mechanics, including the set of contract parameters that

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generate specific dynamics for that agreement [5]. The second category is what we call outcomes-based agreements, which can be seen as a subset of what has been called performance-based risk-sharing arrangements. The third category is coverage with evidence development (CED), which has been used in the United States and Sweden [7]. CED arrangements, in which a positive coverage decision is based on the collection of additional evidence (only with research or only in research), might result in continued, expanded, or withdrawn coverage [7]. Moreover, interest in MEAs is growing due to increasing cost pressures, the need to balance the interests of patients, clinicians, manufacturers, and other stakeholders, as well as the need for addressing uncertainties and incomplete information at the time of decision making [6].

Despite the potential advantages of MEAs, several studies have addressed challenges of MEA implementation related to high cost of administration, lengthy negotiations, unclear success metrics, and overly complex agreements [8]. Other concerns and limitations are due to lack of transparency of MEA objectives and evaluations, limiting the ability of patients to engage with MEA processes, and limiting the transferability of MEA experiences due to the variability across settings and countries. Major concerns in implementing MEAs surround the uncertainty involving management of budget impact for optimal performance as well as concerns for different stakeholders linked with development of registries, data collection, patient response, and streamlined implementation of MEAs [2]. Financial-based schemes are more commonly used than outcomes-based schemes. For instance, Italy's drug registries have enabled the use of advanced agreements in improving patient access to technologies, although The Netherland's experience with MEAs has been limited due to lack of data collection and registries and Poland's current agreements are mainly financial-based, involving simple discounts to make products more affordable [8].

Although some information on MEAs exists in a European context, little is known about experiences with MEAs in Middle East and North African (MENA) countries, where lengthy registration processes for product market entry from foreign pharmaceutical companies have been frequently addressed. In addition, the frequent use of external price referencing to control pharmaceutical prices has been studied in MENA countries, and a recent survey analysis revealed that such a practice has been leading to higher pharmaceutical prices in lower income countries compared to nonpharmaceutical services [9].

This study had two major objectives. The first is to describe current MEA activity in the MENA region as well as pharmaceutical decision-makers' perception and use of these agreements. The second is to describe the challenges and reflect the uncertainty related to MEA implementation as well as the future outlook for MENA activity in the region.

Methods

A prospective cross-sectional survey was conducted between December 2015 and April 2016 in the MENA region. A questionnaire was sent via SurveyMonkey to several pharmaceutical manufacturers and public officials involved in pricing and reimbursement of pharmaceuticals in the MENA region, namely Algeria, Egypt, Lebanon, Jordan, United Arab Emirates (UAE), and Kingdom of Saudi Arabia (KSA). The taxonomy of performance-based schemes introduced by Carlson et al. [4] was adapted for this study. This research utilizes financial-based agreements to refer to cost-containment schemes (although respondents most commonly used cost sharing to refer to financial-based cost-containment schemes) and outcomes-based agreement or arrangement schemes to refer to those that measure real-world clinical outcomes. This research also addresses reimbursement conditional to real-world patients' outcome schemes [4].

In order to address and answer this study's two main objectives, the survey was tailored to collect data on MEA current activities in the MENA region, such as the numbers and types of agreements by therapeutic area, data on both payer and pharmaceutical manufacturer decision makers' perceptions on the impacts, data on the major barriers and challenges when conducting MEAs, and data on predicted future outlook of MEA projects in some MENA countries. Furthermore, the survey gathered information on matters addressed by MEAs related to diminishing uncertainties surrounding new health technologies, such as budget impact, clinical impact, and cost-effectiveness impact. The survey included the different forms and names of MEAs, i.e., risk-sharing agreements, performance-based agreements, and patient access schemes. Participants were identified from the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Arab Network and were then contacted to inquire about their willingness to fill out the survey. A cover letter was sent by email to participants, detailing the purpose of the survey, the estimated time commitment required for survey completion, and reassurance regarding confidentiality policies. This study has been approved by the Lebanese American University Institutional Review Board.

Participants were asked to voluntarily and anonymously fill out the predesigned survey, which included 22 questions to mostly capture 1) types and number of agreements implemented by therapeutics areas and 2) information on matters addressed by MEAs related to uncertainty, such as budget impact, clinical impact, and cost-effectiveness impact. In addition to the primary objectives, the survey addressed the challenges and barriers to implementing MEAs as well as stakeholders' perspectives and outlooks. The scale adopted to measure the study's objective on matters addressed by MEAs as they relate to uncertainty ranged from "most valuable" to "least valuable." Variables were summarized using frequencies and percentages. The survey, followed by several reminders, was sent to 70 potential participants, and then results were generated from completed surveys.

Results

A total of 44 participants (62%) responded to the mailed survey, of which 25% were from the public sector, with the remainder from the pharmaceutical industry. The public sector represented five countries from the region and the pharmaceutical sector represented all countries from the MENA region. Only 42% of participants reported having an MEA running in their institution, the majority representing Lebanon (8 out of 11 respondents). All respondents reported the use of financial-based agreements, most referring to "discounted treatment" and, to a lesser extent, a "price volume agreement." These financial-based agreements were reported as either the only type of MEA (71.4%) being used or as being used with outcomes-based agreements (28.6%). None of the participants reported the use of the latter as the only MEA type. Fifty percent of participants reported one year of experience in MEA implementation. These agreements were considered exceptions by 54.5% of institutions and as general rules, when needed, by 36.4%. Furthermore, the findings showed that agreements are mainly conducted for severe diseases (58.3%), chronic diseases (41.7%), and orphan drugs (25%), and are mostly being initiated by pharmaceutical industries or along with payers (53.8%) (Table 1).

The most favorable financial-based agreement was discounted treatment, and the most favorable outcomes-based agreement was coverage with evidence development or evidence with research. The majority of manufacturer participants