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The Use of Economic Evidence to Inform Drug Pricing Decisions in Jordan

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ABSTRACT

Background: Drug pricing is an example of a priority setting in a developing country with official requirements for the use of cost-effectiveness (CE) evidence. **Objective:** To describe the role of economic evidence in drug pricing decisions in Jordan. **Methods:** A prospective review of all applications submitted between November 2013 and May 2015 to the Jordan Food and Drug Association's drug pricing committee was carried out. All applications that involved requests for CE evidence were reviewed. Details on the type of study, the extent, and whether the evidence submitted was part of the formal deliberations were extracted and summarized. **Results:** The committee reviewed a total of 1608 drug pricing applications over the period of the study. CE evidence was requested in only 11 applications. The submitted evidence was of limited use to the committee due to concerns about quality, relevance of studies, and lack of pharmacoeconomic expertise. There were also no clear rules describing how CE would inform pricing decisions. **Conclusions:** Limited local data and health economic experience were the main barriers to the use of economic evidence in drug pricing decisions in Jordan. In addition, there are no official rules describing the elements and process by which the CE evidence would inform drug pricing decisions. This study summarized accumulated observations for the current use of economic evaluations and evidence-based decision making in Jordan. Recommendations have been proposed to applicants and key decision makers to enhance the role of economic evidence in influencing health policies and evidence-based decision making across priority settings.

Keywords: CE evidence, drug pricing, economic evaluation, evidence-based decision making, Jordan, pharmacoeconomic evaluations, priority setting.

Introduction

Jordan is a developing country in the Middle East placed among middle-income countries of the world, with a population of 6.53 million as in 2013, excluding Syrian refugees who fled their homes since the outbreak of civil war in March 2011 [1–3]. Its gross domestic product (GDP) amounts to 22 billion Jordanian dinars (JD) (US $31 million), and the per-capita GDP is 3438 JD (US $4857). The total health expenditure is around 8% of the GDP, and the total pharmaceutical expenditure accounts for 2% of the GDP and makes up 27% of the total health expenditure, which is estimated to be more than 445 million JD (US $642 million) [3]. Compared with the estimates of any other average country of the World Health Organization Eastern Mediterranean Region, these estimates are considerably high [2,4]. Therefore, the rising burden of health issues and the need to provide equitable access to affordable drugs have been placing great pressure on seeking effective cost-containment strategies [3]. The use of economic evaluations of pharmaceutical products, or pharmacoeconomics, in decision making has been increasing over the years in developed countries to help in containing costs and improve efficiency within a high-budget constraint [5–7]. Empirical studies, however, show that the use of health economic information in health policy decision making in developing countries is still toddling its way. This is mainly due to the lack of skilled health economists and unavailable or fragmented data [8–12]. Jordan is no exception. An exploratory case study from Jordan in 2012 by Lafi et al. [13] evaluated the use of economic evaluations in compiling a rational drug list, which serves as a vehicle to help the government to purchase clinical and cost-effective medicines that match the health needs of Jordanians. This is a priority setting but with no requirements at all for cost-effectiveness (CE) evidence submissions. Lafi et al. did not find economic evidence to be influential in formulary decisions in any way. Since 2012,

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however, a number of political and economic changes have happened, affecting policies and the perspective of key stakeholders in Jordan [1–3]. Drug pricing decision with no previous knowledge of the role and the use of economic evidence within this setting can be recognized as another area of high priority setting in Jordan.

The Jordan Food and Drug Association (JFDA) is the public directorate that is responsible to guarantee safety, quality, efficacy, and pricing of drugs at affordable prices in the local Jordanian market. To approve a price for a pharmaceutical drug, the JFDA drug pricing committee reviews the lowest price among the following: the price in the country of origin, the median benchmark price in the predefined 16 countries, and the price in Saudi Arabia, which has a highly regulated and the largest pharmaceutical market in the Arab region and is in a better negotiation position. This should be followed as per the official pricing policies set by the JFDA and approved by the Prime Minister in 2007. In 2012, the pricing policies were modified. For the first time CE evidence was required to inform decisions of drug pricing when a new drug was available only in the country of origin and in three of the benchmark countries. The policies also specified that a premium price could be fixed over any of the aforementioned prices for any new drug that demonstrated additional clinical and therapeutic benefits through CE studies [14].

The JFDA drug pricing committee consists of decision makers from the Ministry of Health who are influential in making public decisions concerning the purchase and supply of drugs, the JFDA drug division director, the head of the pricing department, a clinician with internal medicine expertise, a pharmacologist or clinical pharmacist, and two pharmacoeconomists. The requirement for two pharmacoeconomists to be in the committee to aid in economic decisions is emphasized by the Drug and Pharmacy Law in Jordan since 2012 [15]. This is the highest official regulatory document for drug use and handling in Jordan. In the cases that require CE evidence, the committee officially corresponds with the applicants, requesting them to provide CE evidence. The submitted evidence is evaluated independently by all the members of the committee over a week. The pharmacoeconomists report to the committee the critiques of the submitted evidence with respect to quality and relevance. The committee discusses the information until consensus is achieved. The decision is then communicated officially in writing to applicants within a month. Within 3 months, applicants should respond officially by either accepting the offered price or requesting further negotiation. The meetings are not open to public; therefore, it is not clear how the economic evidence influences pricing decisions and which elements are considered in the formal deliberations. This study aimed to describe the role of economic evidence in drug pricing decisions in Jordan, an example of a priority setting in a developing country where official policies laid in place request CE evidence in certain situations. It also investigated the barriers to the use of economic information and identified the extent to which the results of economic evaluations are used in high-priority-setting decision making.

Methods

A prospective review of all applications submitted between November 2013 and May 2015 to the drug pricing committee of the JFDA was carried out. All applications that involved requests for CE evidence were reviewed and discussed. Details were recorded after each committee meeting by the author, who is a member of the committee. The following details were recorded: the drug name, the evidence submitted, the price requested, and the price approved by the committee. The extent of the study and whether the evidence submitted was part of the formal deliberations as well as comments on the quality or appropriateness of the submitted evidence were also recorded. Data were extracted using a predefined validated tool designed for the purpose of the study (see Appendix 1 in Supplemental Materials found at http://dx.doi.org/10.1016/j.jval.2015.11.007).

The author, who is a member of the committee, recorded all the comments and details and the rationale for the decisions

Table 1 – Summary of submitted economic evidence reviewed by the JFDA drug pricing committee during November 2013 to May 2015.

	Class/form	Evidence submitted	Ratio of requested price and price of the comparable substitute (comparator)
1	Antihistamine/eye drop	Value dossier	2.14
2	NSAID/tablet	Animal experimental model	1.93
3	Sumatriptan/ injectable	Efficacy, safety, and postmarket studies plus consumer report	2.2
4	Metformin + glibenclamide/ tablet	Cost-utility analysis	2.12
5	Multivitamin/tablet	Applicant's own comparative report	2.38
6	HQ + FA + RA cream	CE study of the originator brand plus applicant's self-reported cost analysis	2.40
7	Metformin + vildagliptin/tablet	Comparative clinical efficacy study with monotherapy	2.3
8	Prednicarbate	Noncomparative clinical efficacy study	No similar generic or originator available in the market*
9	Budesonide + formoterol inhaler	Comparative clinical efficacy study with monotherapy	1.2
10	Citicoline/injectable	CE study of oral citicoline vs. placebo	1.57
11	CCB/injectable	Safety and clinical efficacy review	No similar generic or originator available in the market*

CCB, calcium channel blocker; CE, cost-effectiveness; FA, fluocinolone acetonide; HQ, hydroquinone; JFDA, Jordan Food and Drug Association; NSAID, nonsteroidal anti-inflammatory drug; RA, tretinoin.

* Left the decision of pricing for the committee estimation; for those the committee advocated a price equal to comparators or the therapy that prescribers would mostly replace the proposed drug with.