VALUE IN HEALTH REGIONAL ISSUES 2 (2013) 319–327

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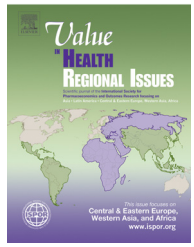

CONCEPTUAL PAPER

Recommendations for Reporting Pharmacoeconomic Evaluations in Egypt

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ABSTRACT

Objective: Introduction of economic evaluations for pharmaceuticals or other health technologies can help the optimization of outcomes from resource allocations. This article aims to provide recommendations for researchers in presenting pharmacoeconomic evaluations in Egypt with special focus on pricing and/or reimbursement applications of pharmaceuticals. **Methods:** The Minister of Health approved the initiative of establishing a focus group of decision makers that included academic and industry experts with experience in health economics, pharmacovigilance, and clinical pharmacy. The focus group has reviewed 17 economic evaluation guidelines available on the Web site of the International Society for Pharmacoeconomics and Outcomes Research for reporting health economic evaluations. To develop core assumptions before preparing a draft report, focus group meetings were held on a regular basis starting June 2012. The recommendations were developed by using the Quasi-Delphi method, taking into account current practices and capacities for conducting pharmacoeconomic evaluations in Egypt. **Conclusions:** Worldwide, health care decision makers are challenged to set priorities in an environment in which the demand for health care services outweighs the allocated resources. Effective pharmaceutical pricing and reimbursement systems, based on health technology assessment (HTA) that encompasses economic evaluations, are essential to an efficient sustainable health care system. The Egyptian Ministry of Health and Population was encouraged to establish a pharmacoeconomic unit, as an initial step, for the support of pricing and reimbursement decisions. We anticipate that standardization of reporting would lead to a progressive improvement in the quality of submissions over time and provide the Egyptian health care system with health economic evidence often unavailable in the past. Therefore, recommendations for pharmacoeconomic evaluations provide an essential tool for the support of a transparent and uniform process in the evaluation of the clinical benefit and costs of drugs that do not rely on the use of low acquisition cost as the primary basis for selection. These recommendations will help inform health care decisions in improving health care systems and achieving better health for the Egyptian population.

Keywords: economic evaluation, Egypt, recommendations, reporting.

Introduction

Egypt's general budget devotes limited amounts to the health sector. In the period 2008 to 2009, Egypt spent LE 61.4 billion (Egyptian pounds) on health, which represents 5.9% of the country's gross domestic product. Out of the total health care expenditure, pharmaceutical expenses constitute a large portion, 34%. [1]. In addition, over the past 16 years, the share of out-of-pocket spending in total health spending has increased dramatically from 51% to 72% [2]. These numbers suggest the increasing need for optimizing the limited resources available. With the growing public demand for improving health care services and reducing the out-of-pocket expenses, economic evaluations of pharmaceuticals and health technologies are critical for efficient allocation of the limited resources.

To better allocate resources and with the growing awareness of the importance of health technology assessment (HTA), the Ministry of Health and Population (MOHP) established a pharmacoeconomic unit to support and inform pricing and reimbursement decisions [3]. No economic evaluations guidelines or standards, however, have been set up yet.

This article provides recommendations based on reviewing other countries' national guidelines for economic evaluation as well as experts' opinions. Other factors influencing the feasibility of conducting such studies in Egypt, including the complexity of the health sector, the availability of data on health care outcomes

Conflicts of interest: 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

http://dx.doi.org/10.1016/j.vhri.2013.06.014

and the costs data, and current capacities for conducting pharmacoeconomic evaluations, were put into consideration in developing these recommendations.

Objective

This article aims to provide recommendations for researchers to present pharmacoeconomic evaluations in Egypt with special focus on pricing and/or reimbursement applications of pharmaceuticals. Policymakers are encouraged to consider these recommendations in developing the national guidelines for the economic evaluation of pharmaceuticals.

Methods

As a self-initiated activity by government personnel, with the approval of the Ministry of Health at the time, a focus group was formed. The aim of the focus group was to develop a set of recommendations and standards for economic evaluation studies used in applying for reimbursement and coverage to 1) promote the concept of combining efficacy, safety, effectiveness, and economic evaluation in the decision-making process; 2) provide instructions for drug manufacturers: how to supply information directly to health care decision makers to support the use of their products; and 3) emphasize that simple assessment of acquisition cost is not a sufficient approach for the control of overall health care expenditures.

To develop the recommendations, two steps were undertaken. The first step was to review the available national economic guidelines. It included a review of 17 recently published national economic evaluation guidelines for conducting and reporting of economic evaluations (Table 1) that included an English version available on the Web site of the International Society for Pharmacoeconomics and Outcomes Research [4].

The second step was to solicit inputs and feedback from key leaders and stakeholders through focus groups. For a comprehensive representation of key stakeholders in health care, focus groups included decision makers experienced in health economics, pharmacovigilance, and clinical pharmacy, health providers as well as researchers and experts selected from both industry and academia, as shown in Table 2.

A consensus approach developed by using the Quasi-Delphi method consisted of an iterative series of meetings and interrogations. Anonymous responses were synthesized into a series of statements. Then, the synthesized statements were submitted to the focus group members for comment until convergence or stasis of opinion was identified in the third round.

Starting June 2012, focus group meetings were held on a regular basis to develop core assumptions before preparing a draft report. The discussions were recorded in written minutes. The recommendations were developed by consensus approach, taking into account current practices and capacities for conducting pharmacoeconomic evaluations in Egypt.

Developing Recommendations for Reporting Pharmacoeconomic Evaluations

Disease and Product Background

Economic evaluations should provide information about the epidemiology of the disease and treatment pathways according to most recent treatment guidelines. Data on the product should include pharmacological class, proposed dosing regimen, route of administration, and results of clinical studies performed to date [5].

Study Design

The study question should address the needs of the decision makers by clearly establishing the context of the study. It should provide details of the study perspective, the proposed product and its comparator(s), the target population, and the effect on specific subgroups where appropriate. Secondary questions that relate to the primary study question should be clearly stated [6].

Perspective should be relevant to the research question and adapted to benefits gained by the health care system. The perspective adopted should maximize the health gain for the population while representing the most efficient use of the finite resources available to the Ministry of Health [7]. It should include direct medical costs as well as additional costs, savings, or other benefits when data are available.

The proposed product should be used primarily in the approved indications with detailed information about its

Table 1 – Focus group members' information.

Member of Focus Group	Degree	Title	Organization	Government Employee
Gihan H. Elsisi	MSc	Head of Pharmacoeconomic Unit	Central Administration for Pharmaceutical Affairs, Cairo, Egypt	Yes
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Mahmoud D. Elmahdawy	PharmD	Manager of Hospital Pharmacy Administration/Part Time Lecturer of clinical pharmacy	Central Administration for Pharmaceutical Affairs/Misr International University, Cairo, Egypt	Yes
Amr Saad	MSc, PhD	Head of Pharmacovigilance Center	Central Administration for Pharmaceutical Affairs, Cairo, Egypt	Yes
Samah Ragab	MPA	Director of the Technical Support Office	Central Administration for Pharmaceutical Affairs, Cairo, Egypt	Yes
Amr M. Elshalakani	MBBch, MSc, MBA	Head of Health Economics Unit	Ministry Of Health, Cairo, Egypt	Yes
Sherif Abaza	MBA	Market Access & Governmental Affairs Manager	Hoffmann-La Roche Ltd. Cairo, Egypt	No