VALUE IN HEALTH REGIONAL ISSUES 16 (2018) 1–11

Available online at www.sciencedirect.com

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Comparing Use of Health Technology Assessment in Pharmaceutical Policy among Earlier and More Recent Adopters in the European Union

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ABSTRACT

Objectives: To examine and compare the use of health technology assessment (HTA) for the reimbursement of new medicines in selected European Union member states with decades of experience in the use of HTA and in countries that have used it regularly since 2000. **Methods:** The selected countries were categorized into "earlier" adopters (group A: England, Germany, France, and Sweden) and more "recent" adopters (group B: Poland, Bulgaria, Hungary, and Romania). A systematic review of published literature was performed. The analysis and comparison of HTA procedures were done by using an analytical framework. **Results:** In all countries, the assessment criteria used include effectiveness, safety, relative effectiveness, and economic data. In group A countries, the main objectives are improving quality of care, ensuring equal access, and efficient use of resources. Group B countries have established HTA organizations with official guidelines but often seek the decisions of other developed countries. They place considerable emphasis on the budget impact of new therapies, and HTA is also used as a cost estimation tool for state budgets. **Conclusions:** HTA organizations have been developed dynamically not only in high-income countries but also in countries with limited resources. The experience and evolution of both can be used by countries that are in the dawn of creating an HTA organization.

Keywords: health policies, health technology assessment, pharmacoeconomics, reimbursement.

Introduction

Health technology assessment (HTA) is considered a key tool used for decision making in health care policy, which can support the efficient use of resources while rewarding innovation. A key purpose of HTA in decision making is to achieve greater value for the money spent [1]. Over the past 30 years, several European countries have established specific bodies and developed various programs for the implementation of HTA [2]. There are, however, considerable differences between national HTA agencies among European Union (EU) member states. The differing philosophy of these organizations is the result of political, social, and economic factors that have shaped European health systems [3].

A systematic comparison of HTA processes applied in decision making on the pricing and reimbursement (P&R) of medicines can identify similarities and differences that provide important information about the stages of development of this complex and multifactorial process. The aim of the present study was to compare how HTA is implemented in the procedures for reimbursement of medicines in selected countries at different levels of maturity in the application of HTA. The purpose of this exercise was to contribute to the evidence base that can be used in the process of planning and introducing an HTA system in a country, as in the case of Greece, which has a constricted health care budget and is in the process of institutionalizing HTA in decision making for the reimbursement of pharmaceutical products. We aimed to provide a snapshot of the selected HTA systems' organization, the procedures and evaluation criteria applied, and the role of HTA in the decision-making process; another question of interest was whether and in what way the characteristics of the HTA systems differ between countries that are at a different stage of HTA implementation. A detailed comparison of analytical methods and techniques applied during the HTA process as well as the actual result of the reimbursement decisions per se were out of the scope of the present analysis.

Conflicts of interest: The authors confirm that there are no known conflicts of interest associated with this publication that could have influenced its outcome. The views expressed in this article are those of the authors and not of the organizations or company that they may serve.

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2212-1099/$36.00 – see front matter

https://doi.org/10.1016/j.vhri.2018.08.002

Methods

Criteria for the Selection of Countries

The first criterion was the countries' political-geographical position; the countries selected were members of the EU. Second, given that the Greek legislation provides for a centrally organized HTA organization, countries with regionally organized HTA procedures were excluded. To account for different levels of maturity in the application of HTA, the number of years of experience in HTA implementation (not limited to decision making on pharmaceuticals) was considered. Sweden, France, the United Kingdom, and Germany are considered leaders in the establishment of HTA in Europe and have also been very influential regarding the methods and tools applied in HTA and its use in policymaking [2]. Selected Central and Eastern European countries were included because they constitute "recent adopters" of HTA.

On the basis of the aforementioned criteria, the following countries and their respective HTA agencies were selected: France (*Haute Autorité de Santé* [French National Authority for Health]), Germany (*Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen* [German Institute for Quality and Efficiency in Health Care]), the United Kingdom (National Institute for Health and Care Excellence [NICE]), Sweden (*Tandvårds- och läkemedelsförmånsverket* [TLV; Dental and Pharmaceutical Benefits Agency]), Bulgaria (National Centre of Public Health Analysis), Hungary (Technology Appraisal Head Department), Poland (*Agencja Oceny Technologii Medycznych i Taryfikacji* [Agency for Health Technology Assessment and Tariff System]), and Romania (HTA unit of the National Drug Agency). Two groups were formed: group A included the "earlier" adopters (France, Germany, the United Kingdom, and Sweden), whereas group B included the "recent" adopters (Bulgaria, Hungary, Poland, and Romania).

Collection of Information

Information was collected through a systematic literature review that applied modified guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses. An extensive search using a structured search strategy was performed for peer-reviewed articles published in English during the last 15 years (from January 2000 to February 2015).

English terms including specific conditions (i.e., Medical Subject Headings terms) combined with free-text terms were used: the selected "country," with the phrases "health technology assessment" or "HTA," "health policy," "pharmaceutical policy," "pricing and reimbursement," "health reform," "pharmaceuticals reimbursement," "economic evaluation," and "impact on health budget" [4]. The first extensive search was done in PubMed, from which most of the included articles were recovered. An additional search was done in the following specialized journals: *International Journal of Technology Assessment in Health Care* and *Value in Health* (main and regional issues). Finally, manual search was performed by checking the list of references in the articles identified as satisfying all the inclusion criteria.

All recovered abstracts were reviewed independently and, subsequently, full-text articles were identified on the basis of specific inclusion and exclusion criteria. Articles were included if they 1) were in English, 2) were related to the implementation of HTA for decisions on medicine reimbursement, and 3) were published between January 2000 and February 2015. Articles were excluded if 1) articles presented results of economic evaluations of medicines and medical devices, 2) HTA implementation was in a hospital setting, and 3) full text was not accessible. The independent review was performed online by using Covidence, which is a tool for the organization and evaluation of information gathered in the context of a systematic literature review. When there were disagreements, the final decision was made after a discussion among all authors. A search for supplementary information was performed in HTA organizations' Web sites and guidelines (where available in English and in other cases with the use of Google Translate) and in the Web sites of the International Society for Pharmacoeconomics and Outcomes Research, the Organization for Economic Cooperation and Development, and the European Observatory on Health Systems and Policies.

Methods of Comparative Analysis

For the analysis and comparison of HTA processes in the selected countries, an adapted methodology developed by Hutton et al. [5] and modified by Franken et al. [6] was used. According to the Hutton framework, data are displayed in tables where the main characteristics of the HTA systems are depicted so as to facilitate comparison [5,6]. In this context, the organization of an HTA agency is split into two levels of analysis—the policy implementation level and the individual technology decision level. The policy implementation level concerns the way in which HTA is embedded in the broader political system, the HTA agency's legal status, and its relationships with other public sector bodies and stakeholders (such as industry and patient groups) and also provides information as to what the purpose of the HTA organization is, whom does it advise, and to whom it is accountable [5,6]. The technology decision level comprises the processes by which individual technologies are evaluated by the system, for example, assessment processes, how decisions are made, and how they are implemented [5,6]. Franken et al. [6] also differentiated between an assessment and an appraisal phase in the HTA process.

Results

A total of 1724 articles were identified for initial review. Of these, 309 were duplicates and thus excluded. By applying the inclusion and exclusion criteria, 1165 articles were excluded after the assessment of abstracts, resulting in 249 articles for full-text evaluation. Applying the same independent assessment process, 64 articles were found to fully satisfy the inclusion criteria. An additional nine articles were identified after checking the reference lists of included articles. Thus, finally 73 articles were used in the analysis. The collected information was analyzed and classified according to the two dimensions of the Hutton framework.

A schematic representation of the search and selection process is shown in Figure 1.

Policy Implementation Level

The main characteristics of the political implementation level for the countries of groups A and B are presented in Table 1.

In England, France, and Germany, the HTA bodies are public bodies that operate independently from the government, whereas in Sweden the TLV is a governmental agency. All four HTA bodies in group A countries were established by government bodies in the context of broader reforms toward evidence-based medicine, improvement of safety and quality of care, as well as promotion of equity and efficiency in the use of health care budgets [7–11]. HTA was seen as a tool toward achieving these goals while rewarding innovation and has an important role in the decision-making process [9,11–15]. This is reflected in the organizations' objectives and scope of activities, which are broader than the assessment of medicines. These organizations also place emphasis on operating with processes and procedures that are considered best practice (e.g., independence, transparency, and openness) [2,4,6,14,16–19].