Health Policy 102 (2011) 145–151

Contents lists available at ScienceDirect

Health Policy

journal homepage: www.elsevier.com/locate/healthpol

A review of Health Technology Assessment (HTA) recommendations for drug therapies issued between 2007 and 2009 and their impact on policymaking processes in Poland

Katarzyna Kolasa[a,*], Sebastian Schubert[b,1], Andrea Manca[c,2], Tadeusz Hermanowski[a]

[a] Department of Pharmacoeconomics, Medical University of Warsaw, 3a Pawinskiego St., 02-106 Warsaw, Poland
[b] Warsaw School of Economics, Poland
[c] Centre for Health Economics, Alcuin 'A' Block, University of York, Heslington, York, YO10 5DD, UK

ARTICLE INFO

Keywords:
HTA
Policymaking
Reimbursement
Poland

ABSTRACT

Objective: The primary objective of this study was to critically review and analyze the Polish Health Technology Assessment (AHTAPol) agency's health technology drug recommendations (HTA activity), in order to ascertain to what extent HTA findings have been incorporated into national drug reimbursement decisions (HTA impact).
Methodology: HTA recommendations issued between 2007 and 2009 were studied. Positive recommendations were classified into three categories: recommendations with major restrictions; minor restrictions; and without restrictions. Definitions of clinical and non-clinical reasons were drawn ups for negative recommendations. The study examined how many different drug technologies assessed by AHTAPol were included in reimbursement lists.
Results: In terms of HTA activity, 63 negative and 83 positive HTA recommendations were issued. While clinical arguments were the most prevalent reason for negative HTA recommendations, major restrictions were most common in the positive guidance group. In terms of HTA impact, the results revealed 30 drugs with positive HTA recommendations and four with negative HTA recommendations were included on the reimbursement lists.
Conclusions: Most of AHTAPol's recommendations have a positive outcome for the drug being appraised. The study revealed room for further enhancement of HTA impact. Three key areas that need future attention were identified: consistency, credibility; and pragmatism.

1. Introduction

Although factors such as equity, access and safety play a critical role in many decision-making processes around the world, affordability remains a fundamental consideration. As the pressure on health care budgets increases, Health Technology Assessment (HTA) becomes an important tool for achieving efficient use of healthcare resources [1–3]. HTA is concerned with the medical, organizational, economic and societal consequences of implementing health technologies or interventions within a given healthcare system [4]. It aims to provide an effective way to generate relevant input into the decision-making process concerning reimbursement and pricing, as well as the development of clinical practice guidelines [5,6].

The primary objective of this manuscript is to describe the outcomes of the HTA process in Poland (HTA activity).

* Corresponding author. Tel.: +48 022 57 20 855; fax: +48 022 57 20 855.
E-mail addresses: kkolasa@wum.edu.pl, katarzyna.kolasa@bms.com (K. Kolasa), sebschubert@o2.pl (S. Schubert).
[1] Tel.: +48 22 579 6767; +48 606 688 681 (mobile).
[2] Tel.: +44 01904 321401; fax: +44 01904 321402.

0168-8510/$ – see front matter © 2011 Elsevier Ireland Ltd. All rights reserved.
doi:10.1016/j.healthpol.2011.05.001

'Outcomes' being understood to be the same as the approach proposed by Hailey and colleagues [7]. The authors argued that the best approach for measuring HTA activity is in fact to quantify the number of HTA recommendations published as a result of the appraisal process. Even though the study of HTA activity is interesting in itself as it provides valuable insight into the quality of the HTA process, it could also be considered a prerequisite to any analysis assessing the impact of HTA outcomes.

The secondary objective of this paper is to assess to what extent HTA recommendations have been incorporated into the decision making process concerning public financing of different technologies (HTA impact) in Poland. HTA impact is often defined as the extent to which evidence-based guidance is adopted and how much this translates into direct effects on the healthcare system and health outcomes [8,7] More specifically, HTA impact could be characterized by answering the following questions: *Do policy-makers consider HTA outcomes in the pricing and reimbursement decision making process?, Do policy-makers accept HTA recommendations?*, and finally, *Are HTA outcomes incorporated into policy or administrative decisions?*

The impact of HTA should be regarded as an important result of the HTA process. Jacob and McGregor [9] point out that "...however excellent an HTA may be, if it fails to influence the working of the health care system, it is without impact and must be considered without value...". According to Wanke and colleagues [8], HTA impact could be characterized as a three-step process. At the first level, the desired outcome is to ensure the decision-makers and the public are aware of and satisfied with the HTA agency's work. The second level refers to the utilization of HTA outcomes (symbolic, conceptual and instrumental utilization). The third level of HTA impact is achieved when HTA recommendations result in changes in the research and development (R&D) process, or adaptation or obsolescence of a given technology.

The paper is structured as follows: the first part provides a brief overview of the HTA process in Poland, while Section 3 presents the approach used to study HTA activity and impact. The results of the review are presented next, and the final section highlights the key findings of the study and provides suggestions for future improvements to the HTA process in Poland.

2. Background

The requirements of evidence based medicine as well as budget impact analysis were legally introduced into the Polish pricing and reimbursement system for health care services in 2004. Since then, HTA in Poland has become an important part of the decision-making process relating to the diffusion of drug technologies. The HTA agency (AHTAPol) was established in 2005 by an ordinance of the Ministry of Health (MoH) [10].

The main objective of AHTAPol is to provide the MoH with reimbursement recommendations based mainly on the results of the HTA report submitted by the manufacturer [11].

The current version of the HTA methodological guideline was published by AHTAPol in January 2010 [12]. According to this guidance document an HTA report produced for consideration by AHTAPol should include a scoping systematic review, an economic analysis (mainly CEA or CUA) and a budget impact analysis.

Generally, there are two types of reimbursement list in Poland: the retail drugs list and the healthcare programs list. Both are prepared and updated periodically by the MoH [11]. The retail drugs reimbursement list consists of more than three thousand drugs to be used in outpatient care settings, with no limitations in terms of volume of prescription. The healthcare programs lists are designed for costly therapies to be used in hospital settings. There are strictly defined inclusion and exclusion criteria for patients to be treated with drugs included in the healthcare program list. While there are different levels of copayments for retail drugs (0%, 30%, 50%), there are no out-of-pocket payments for drugs available within healthcare programs.

The reimbursement process starts with the manufacturer submitting a reimbursement and pricing application to the MoH along with an HTA report (Fig. 1). Applications for new chemical entities (NCE) for specific indications (i.e. EMEA's decision on marketing authorization and its recommendations on the conditions of use) that are not yet reimbursed should include an HTA report. After an initial formal assessment of its content, the MoH sends the HTA report to AHTAPol. Assessment of it is carried out by the analytical team at AHTAPol (Fig. 2). Next, an appraisal is conducted by the Consultative Council (Appraisal Committee) – an independent advisory body consisting of external experts invited by the MoH [11]. The Appraisal Committee subsequently takes into consideration the HTA report submitted by the manufacturer, and the report produced by the analytical team at AHTAPol together with the manufacturer's comments and the opinion of clinical experts. The Appraisal Committee's final HTA recommendation is then communicated to the Drug Management Team (DMT), an advisory body within the MoH, which is responsible for price negotiations. While HTA recommendations are not mandatory in Poland, the DMT issues a recommendation regarding whether the drug should be reimbursed and, if so at what price [13], and then the MoH makes a final reimbursement decision. Polish law stipulates that the MoH should update the list of reimbursed drugs four times a year (every 90 days), but in practice this usually happens twice a year [14].

3. Methods

To evaluate the impact of HTA activity in Poland, the primary objective of the paper, we adopted an approach used by Raftery [15] in which HTA recommendations were classified according to specific criteria. An adjustment of Raftery's classification was made to fit the Polish setting based on the preliminary review of all HTA recommendations published in Poland between March 2007 and January 2010. More specifically, HTA recommendations were classified into one of the following groups:

I. *Negative recommendation* (i.e. the Appraisal Committee does not recommend financing the drug from public funds). These can either be based on clinical grounds (e.g. insufficient clinical effectiveness data, poor efficacy