Health Policy 120 (2016) 1249–1255

Contents lists available at ScienceDirect

Health Policy

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

Impact of patient outcomes and cost aspects on reimbursement recommendations in Poland in 2012–2014

Krzysztof Piotr Malinowski, Paweł Kawalec*, Wojciech Trąbka

Jagiellonian University Medical College, Faculty of Health Sciences, Institute of Public Health, Kraków, Poland

ARTICLE INFO

Article history:
Received 18 June 2015
Received in revised form 15 August 2016
Accepted 23 September 2016

Keywords:
Agency for Health Technology Assessment and Tariff System
AOTMiT
Reimbursement recommendations
Health technology assessment
Poland

ABSTRACT

The aim of this study was to assess the influence of different factors on the final reimbursement recommendations for drugs in Poland and to identify the correlation between these factors and the probability of a positive reimbursement recommendation for an applicant drug issued by the President of the Agency for Health Technology Assessment and Tariff System (AOTMiT).

We analysed all recommendations for the period of 2012–2014 in Poland, three years following the launch of the new Reimbursement Act of Medicines, Foodstuffs Intended for Particular Nutritional Uses and Medical Devices. For each recommendation we collected data on efficacy, safety, cost of therapy, cost-effectiveness, quality of evidence, orphan drug status and others. Logistic regression was used to identify factors that increase the odds of a positive reimbursement recommendation.

We analysed 221 recommendations for drugs, of which 78% were positive. We observed significant associations of all selected factors with positive recommendations. Proven efficacy and safety were associated with much greater odds for a positive reimbursement recommendation (123.5 and 42.6, respectively) than cost factors, which may suggest that patient outcome is much more important than the results of the cost-effectiveness analysis (odds ratio of 3.5) and the general cost of therapy (odds ratio of 3) in the analysed period.

1. Introduction

The key policy maker and the regulator in the health care system in Poland is the Ministry of Health, supported by advisory bodies. In 2005, the Agency for Health Technology Assessment (AOTM; AHTAPol) was established, and then reorganized and renamed as Agency for Health Technology Assessment and Tariff System (in Polish, Agencja Oceny Technologii Medycznych i Taryfikacji, AOTMiT). At present the AOTMiT is an independent legal entity that collects data and delivers statements and recommendations on technologies claiming public funding, of which predominant are drugs. The President of the AOTMiT chairs the institution and oversees all its activities. Another important entity within the AOTMiT is the Transparency Council, established in 2012, which is an independent advisory body consisting of 20 highly qualified members providing opinions (statements) for applicant drugs [1]. The AOTMiT delivers reimbursement recommendations issued by the President of the AOTMiT to the Ministry of Health. The role of the AOTMiT in the decision-making process involves the assessment and appraisal of medical technologies claiming public funding, which is consistent with international standards regarding HTA.

* Corresponding author at: Drug Management Department, Institute of Public Health, 20 Grzegórzecka Street, 31-531 Kraków, Poland. Fax: +48 12 42 174 47.
E-mail addresses: pawel.kawalec@uj.edu.pl, ppkawa@poczta.onet.pl (P. Kawalec).

http://dx.doi.org/10.1016/j.healthpol.2016.09.016
0168-8510/

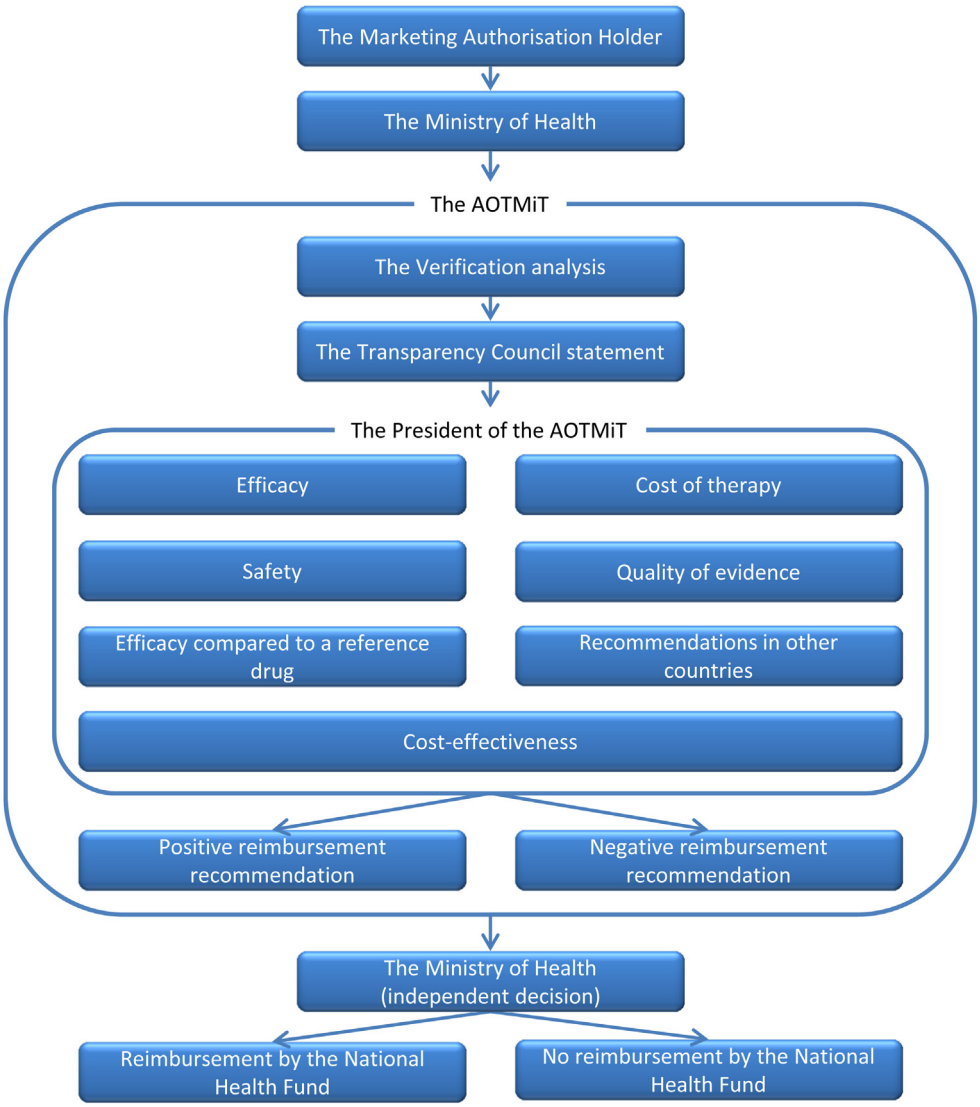

Fig. 1. Flowchart for the reimbursement decision-making system in Poland.

The reimbursement process is initiated by the Marketing Authorisation Holder (MAH), which provides the application form accompanied by a number of attachments, including the HTA report, to the Ministry of Health and then the Ministry of Health provides the HTA documentation to the AOTMiT for verification. A full HTA analysis must contain decision problem analysis, clinical analysis, economic analysis, budget impact analysis, and (if revealed additional expenses for public payer resulting from the reimbursement of the assessed technology) rationalisation analysis (including proposals of changes in the reimbursement system producing savings for public payer balancing costs due to reimbursement decision) must be also provided. During the assessment of the HTA documentation for applicant drug, the AOTMiT analyses clinical efficacy and safety as well as the cost of therapy and cost-effectiveness of a specific drug. The AOTMiT evaluates cost-utility of drugs using a fixed threshold (currently around 30,000 euros), which is calculated as three times gross domestic product per capita (as stated in the Polish Reimbursement Act of Medicines, Foodstuffs Intended for Particular Nutritional Uses and Medical Devices from 2011) per one quality adjusted life year (QALY) gained, obtained owing to the use of a new therapy in place of the existing one. Additionally, recommendations and reimbursement statuses in other countries are also considered by the AOTMiT based on a review of data published by chosen HTA agencies. The stage of the assessment of a medical technology is based on a specially designed and objective methodology according to guidelines and published requirements, without subjective opinions. At the end of the assessment process, a verification analysis based on submitted HTA documentation is produced by the consultancy team of the AOTMiT, which is a basis for statements (issued by the Transparency Council) and recommendations (produced by the President of AOTMiT) which constitute an appraisal stage of the process; in