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Relating Health Technology Assessment recommendations and reimbursement decisions in Poland in years 2012–2014, a retrospective analysis

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ABSTRACT

Objective: The aim of the study was to assess the influence of public advisory bodies (the Transparency Council, the President of the AOTMiT; The Polish Agency for Health Technology Assessment and Tarff System) involved in the process on final reimbursement decisions performed by the Ministry of Health.
Methods: We have analysed all statements of the Transparency Council as well as the President of the AOTMiT recommendations and final reimbursement decisions in Poland for the period of three years: 2012 till 2014. For each recommendation we collected data on decisions as well as potential additional requirements regarding the reimbursement; data was presented for the whole analysed period and separately for each year, to assess the general tendencies in the reimbursement decision-making in Poland. We collected all data accessible at February 2015. The kappa measurement of agreement was used to assess the compliance between statements, recommendations and reimbursement decisions.
Results: We collected data on 238 drugs evaluated by the Agency. The compliance between the Transparency Council and the President of the AOTMiT was 95% and remained constant in the analysed period. The agreement between the President of the AOTMiT recommendations and final reimbursement decisions was only fairly represented by a kappa coefficient of 0.23 and decreased in the subsequent years. We observed an increasing proportion of positive-conditional recommendations, with the introduction of a risk sharing scheme being the most common condition of a reimbursement recommendation.
Conclusions: We observed that final reimbursement decisions did not reflect statements and recommendations issued by the advisory boards. Positive recommendations issued by the AOTMiT did not guarantee positive reimbursement status, and negative recommendations in some cases did not result in the lack of reimbursement.

1. Background

In recent years significant changes in the reimbursement system in Poland have been observed, and the process of implementation of new approaches in the system was dynamic. In 2005, the Polish Agency for Health Technology Assessment and Tariff System (AOTMiT) was established and since 2009 is an independent legal entity which collects data, performs analysis and delivers statements and recommendations on technologies claiming public fund, of which more than 90% are drugs. The principal at the AOTMiT is the President, who leads and oversees all AOTMiT's activities. The other important entity within the AOTMiT is the Transparency Council (TC), established in 2012 (pre-

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viously, it was the Consultative Council of the AOTMiT, founded in 2007), which is an advisory, independent body including 20 highly qualified members: Health Technology Assessment (HTA) experts, as well as members appointed by the Minister of Health, National Health Fund, National Drug Registration Agency and representatives of the Commissioner for Patients' Rights. The role of the AOTMiT in the decision-making process embraces the assessment and appraisal of all medical technologies claiming public money coverage, which is coherent with international standards regarding HTA. The stage of assessment of a medical technology is based on a specially designed and objective methodology accordingly to guidelines and published requirements, without subjective opinions [1]. The appraisal stage is a subjective valuation of medical technology that considers ethical, social and organizational aspects. AOTMiT delivers reimbursement recommendations issued by the President of the AOTMiT to the Ministry of Health.

In the decision-making process, two fundamental documents on HTA methodology are essential – in 2009 AOTMiT incorporated the guidelines for conducting Health Technology Assessment, and although fulfilment of all the requirements stated in this document is not obligatory it is strongly recommended; otherwise HTA has to be in strict accordance with the Regulation of the Minister of Health of 2nd April 2012 on the minimum requirements to be satisfied by the analyses accounted for in the applications for reimbursement and setting the official sales price – an official document with a set of obligatory methodological requirements.

In the reimbursement process in Poland, the Marketing Authorisation Holder (MAH), who initiates the process, has to provide the Ministry of Health with a completed application form accompanied by a number of attachments, including the HTA file (Fig. 1). Then the Ministry of Health passes on the HTA documentation to the AOTMiT, which has no more than 60 days for making the HTA assessment. The Marketing Authorisation Holder has to fill any gaps in the documentation within 14 days of the announcement, and during this period the whole process is on hold. The result of the AOTMiT assessment is the verification analysis which is established by the analytic team of the Agency. This document is then used to formulate the reimbursement statement made by the Transparency Council. On the basis of this statement, the President of the AOTMiT formulates a recommendation. There are three types of recommendations: positive (which support coverage from the public budget), conditional (a positive recommendation but fulfilling some additional conditions is required, such as reducing the cost of therapy or providing additional restrictions to reimbursement; e.g. with an assessment of the clinical effects of therapy after a period of reimbursement) and negative (which recommend no public funding).

In the next step of the decision-making process, the HTA documentation and the recommendation of the President of the AOTMiT are passed to the Reimbursement Economic Committee, which is an advisory body for the Ministry of Health and consists of representatives of the Ministry of Health as well as the President of the National Health Fund. Reimbursement Economic Committee is dedicated to negotiate with the Marketing Authorization Holder the price of a drug, rules for public funding, risk-sharing scheme (RSS) and details of the drug programme if appropriate. For a drug to be reimbursed, it is necessary to reach consensus during these negotiations.

The final decision on reimbursement belongs to the Minister of Health, who can decide whether to include a specific drug on the reimbursement list unconditionally or after fulfilling some additional requirements, such as the RSS or lowering of the official price of the drug. The final reimbursement decision is made independently by the Minister of Health, and there is no legal requirement for this decision to comply with any recommendation or opinion issued by the President of the AOTMiT or the Reimbursement Economic Committee (REC). In other words, a recommendation by the President of the AOTMiT and the opinion of the Reimbursement Economic Committee are formal but not obligatory criteria for the Minister of Health to consider when making reimbursement decisions. The reimbursement process as a whole, from a formal application to the final reimbursement decision, should take no longer than 180 days. The Marketing Authorisation Holder can appeal against the decisions of the Minister of Health, but only in court.

All of the statements by the Transparency Council and recommendations by the President of the AOTMiT are available within the public domain, at AOTMiT's website [1]; the final reimbursement decision is delivered to the Marketing Authorisation Holder, but the current reimbursement status of a drug is published by the Ministry of Health [2], and reimbursement lists are announced by the Minister of Health every two months. Details of negotiations and texts of final agreements between the MAH and the Reimbursement Economic Committee are confidential, and known only to the Ministry of Health. The full legislative process is described in detail in Fig. 1.

Although the final decision on reimbursement belongs only to the Ministry of Health, the advisory boards such as the Transparency Council, the President of the AOTMiT, and the Reimbursement Economic Committee have a significant influence on this decision. It is strongly suspected that their advice is reflected in decisions made by the Ministry of Health.

The objective of this paper was to assess the agreement between the statements of the Transparency Council and the recommendations issued by the President of the AOTMiT, as well as the association between the recommendations and final reimbursement decisions of the Ministry of Health in Poland.

Performing such a study made it possible to assess changes in the decision-making process in drugs' reimbursement in the analysed period, from the year 2012 to the year 2014.

2. Methods

2.1. Data collection and synthesis

We analysed all statements of the Transparency Council, the President of the AOTMiT recommendations and final reimbursement decisions for the last three years from