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Eight-year experience of using HTA in drug reimbursement: South Korea

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ABSTRACT

This study describes the process and results of drug reimbursement decision-making in South Korea and evaluates its performance from the perspectives of the various stakeholders involved. Data were retrieved from the evaluation report posted on the Health Insurance Review and Assessment Service (HIRA) website. As of 2014, 253 new drugs had been submitted to the HIRA for appraisal. Of these, 175 (69.2%) were recommended in favor of listing and 78 (30.8%) were rejected. Furthermore, 68 of these drugs were deemed clinically improved relative to existing drugs. For those drugs that did not demonstrate clinical superiority (which was most of them), a simple price comparison to the existing drug was utilized as a gate toward listing.

On top of the base-line analysis, 104 stakeholders from the industry, academia, public office, and civic society responded to a questionnaire designed to obtain their opinions on the South Korean positive list system (PLS). Stakeholders agreed that the consistency of reimbursement decision-making has improved since 2007, while accessibility to new drugs has apparently decreased. Respondents also indicated a preference toward improved public access to decision-making information. This examination of reimbursement decisions in South Korea will illuminate critical issues for countries that are considering the introduction of similar policies.

1. Introduction

In the face of health care expenditures that are increasing faster than the national income, many countries are critically evaluating the economic value of new medical technologies [1,2] since their introduction and diffusion have been blamed as a key driving factor behind the explosion of medical expenditures [1,2].

In particular, the value of newly developed drugs has been intensely debated because the expenditure on prescription drugs has been increasing faster than other medical expenditures since the 1990s [1], while their innovativeness is frequently doubted. In fact, only a limited number of newly approved new molecular entities (NMEs) have been reported to demonstrate clinically meaningful therapeutic gains [3], which have generated a lot of interest

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regarding their value. As a result, cost-effectiveness has been highlighted by many Western countries as an important factor in reimbursement decision-making in the last two decades.

South Korea joined the trend in the mid-2000s and became the first Asian country to implement the formal process of considering pharmacoeconomic data [4]. In 2006, the South Korean government announced that it was going to implement a "drug expenditure rationalization plan (DERP)" to curb the rapidly rising drug expenditures [4–7], which constitute 23.9% of total health expenditures [4,6–8]. To reign in drug expenditures at a sustainable level, several measures were put in place, and a positive list system (PLS) has been included as part of the DERP [4,5,7].

Before the introduction of the PLS, applications for reimbursement decisions for new drugs were sent to the Health Insurance Review and Assessment Service (HIRA) 30 days after market authorization. Most licensed drugs were listed on the National Health Insurance (NHI) benefit schedule with only a few exceptions, and were priced according to the pre-determined pricing formulae [6]. However, under the PLS, pharmaceutical companies apply to have their new drugs listed on the South Korean NHI at their discretion, and the insurer makes the final decision on whether to list them based on the submitted drugs' value; the PLS was proposed as a means to reinforce the buying power of the insurer [5,9].

Under the PLS, rigorous evaluations of scientific evidence as well as the transparency and consistency of decision-making have been highlighted by stakeholders. The feasibility of the system was questioned in its early stages because the number of experts in relevant areas was limited, and domestic data were insufficient to assess the value of drugs in a local context [4,6]. Namely, in terms of experience and availability, South Korea was no different from other Asian countries when deciding to change its system [10,11].

2. The process of reimbursement decision-making

Once the applications and related dossiers for new drugs are submitted by a company in South Korea, Health Insurance Review and Assessment Service (HIRA) staff review them and assess the drug's clinical effectiveness and cost-effectiveness. The HIRA then sends the reviewer's opinion on the submitted evidence to the manufacturer for comments. Before the cases are placed on the meeting agenda of the Pharmaceutical Benefit Coverage Assessment Committee (PBCAC) — a body that deliberates on the value of submitted drugs and makes a recommendation to the HIRA on whether to list them on the benefit schedule [12] — an economic sub-committee (ESC) reviews the technical aspects of the economic evaluations included in the dossiers [7,9].

According to its guidelines, the PBCAC is expected to consider the therapeutic benefits and cost-effectiveness of the submitted drugs [13]. If they are similar to existing comparators, then the costs of therapeutic alternatives are compared and drugs that are inferior to the existing drugs cannot be listed. If a submitted drug shows it can improve people's health but is more expensive than similar existing drugs, a full economic evaluation is required to verify its value for money; the incremental cost-effectiveness ratio (ICER), the ratio of additional costs to additional QALYs (quality-adjusted life years) compared with alternative treatments, is the preferred measure of cost-effectiveness [14].

To improve the transparency of the decision-making process, several measures have been implemented since 2007. For companies, several opportunities to appeal their product are given. First, they can explain the submitted evidence in a face-to-face meeting with HIRA staff, and responding to HIRA staff's review opinions is also permitted. Moreover, if the submitted drug is rejected, they can ask for reconsideration with updated evidence [13,15]. An independent review process was to begin when the South Korea-U.S. Free Trade Agreement came into effect in which a third independent expert panel is to review the points raised and make recommendations on whether to reconsider drugs during the PBCAC meetings [15]. No cases have been reconsidered through this process as of October 31, 2015.

Once the committee recommends the listing of a submitted drug, the price negotiations between the company and National Health Insurance Service (NHIS) follows. Even if the new drugs are accepted by the PBCAC, they cannot be listed if the price negotiations fail. However, exceptions for "medically necessary drugs" are recognized by the PBCAC [4,7,15], which was a categorization created after the introduction of the PLS to protect the right to access essential medicine. The PBCAC recognizes a drug to be essential in treating patients when it meets all of the following conditions: 1) there are no alternative treatments for the submitted drug; 2) the drug is for severe life-threatening diseases; 3) the drug is used for very rare diseases, and is considered necessary to treat those patients; and 4) the health benefits of the drug are supported by evidence [9,13]. In this event, another independent committee, the Benefit Coordination Committee, determines the price (compulsory listing) considering both parties' position, and the Ministry of Health and Welfare (MOHW) lists the drug on the benefit schedule at the determined price.

This paper aims to diagnose the current state of the South Korean PLS. Some descriptive analysis will be provided to show the distribution of the recommendations made. Then, the performance of the general system will be evaluated according to the conceptual framework of structure, process, and outcome. Finally, we will highlight several issues that have been raised by stakeholders and the government's response to these challenges in the discussion.

The experience of reflecting value and using economic evidence in reimbursement decisions in South Korea will shed some light on these critical issues for countries that are considering the introduction of similar policies.

3. Methods

3.1. Analysis of the PBCAC recommendations

All recommendations made by the PBCAC until December 2014 have been reviewed and analyzed to show