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New decision-making processes for the pricing of health technologies in Japan: The FY 2016/2017 pilot phase for the introduction of economic evaluations☆,☆☆

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ABSTRACT

Economic evaluation is used for decision-making processes in healthcare technologies in many developed countries. In Japan, no health economic data have been requested for drugs, medical devices, and interventions till date. However, economic evaluation is gradually gaining importance, and a trial implementation of the cost-effectiveness evaluation of drugs and medical devices has begun. Discussions on economic evaluation began in May 2012 within a newly established sub-committee of the Chuikyo, referred to as the Special Committee on Cost Effectiveness.After four years of discussions, this committee determined that during the trial implementation, the results of the cost-effectiveness evaluation would be used for the re-pricing of drugs and medical devices at the end of fiscal year (FY) 2017. Chuikyo selected 13 products (7 drugs and 6 medical devices) as targets for this evaluation. These products will be evaluated until the end of FY 2017 based on the following process: manufacturers will submit the data of economic evaluation; the National Institute of Public Health will coordinate the review process; academic groups will perform the actual review of the submitted data, and the expert committee will appraise these data. This represents the first step to introducing cost-effectiveness analysis in the Japanese healthcare system. We believe that these efforts will contribute to the efficiency and sustainability of the Japanese healthcare system.

1. Introduction

In many developed countries, decision-making for healthcare technologies is subject to economic evaluation, which is sometimes performed as part of health technology assessment (HTA) [1]. For example, in the United Kingdom, the National Institute for Health and Care Excellence (NICE) issues technology appraisal guidance for selected drugs and devices, which emphasize cost-effectiveness in addition to effectiveness and safety [2]. Many European and other countries also require the submission of cost-effectiveness data to specific authorities for pricing or reimbursement.

However, in Japan, no specific health economic data have been requested for drugs, medical devices, and interventions [3,4]. Strictly speaking, since 1992, when new medicines were added to the reimbursement list for public healthcare insurance, economic evaluation data could be submitted to the Ministry of Health, Labour and Welfare (MHLW, Ministry of Health and Welfare at the time). This was one of the fastest introductions of economic evaluation given that the Pharmaceutical Benefits Advisory Committee (PBAC) in Australia began considering the results of economic evaluation in 1993 [5].

Despite this, there is a lack of clear rules on how to use the data submitted. In fact, even if economic data are submitted, many pharmaceutical companies believe that such data have little influence upon decisions such as the pricing of their products [6]. Consequently, economic data for only eight new drugs were submitted to the MHLW from FY (fiscal year) 2006 to FY 2011 although

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reimbursement for 256 ingredients was provided during the same period [7].

However, Japan is one of the fastest-aging countries in the world and consequently faces a rapid rise in healthcare expenditure. National healthcare expenditure estimated by the MHLW was approximately JPY 40 trillion (USD 364 billion, 1 USD = JPY110 as of May 2017, Bank of Japan), which accounted for 8.3% of gross domestic product (GDP). As the expenditure was JPY 32 trillion (USD 291 billion) and 6.4% of GDP ten years ago, the expenditure had increased by 25% and the rate had increased by 1.3 times. According to OECD health data, current expenditure of health is 11.2% of GDP, which is the third largest after the United States and Switzerland.[1]

This situation is exacerbated by newly developed and high-priced healthcare technologies such as anti-cancer and anti-hepatitis drugs. This has led to the growing awareness of the importance of economic evaluation and has sparked a trial implementation of cost-effectiveness evaluation (the MHLW refers to economic evaluation as such) for drugs and medical devices from FY 2016. In this paper, we provide an overview of relevant discussions and the process of trial implementation after a brief explanation of the Japanese system of pricing drugs and medical devices.

2. Pricing system for drugs and medical devices

In Japan, all new drugs and medical devices approved by the Pharmaceutical and Medical Devices Agency (PMDA) are generally reimbursed by public healthcare insurance without any cost-effectiveness data. The MHLW determines official reimbursement prices of drugs and medical devices, which are uniform throughout Japan. In a manner which is different from most other countries, the official price is calculated by the detailed pricing rule, not price negotiation. The calculated price is approved by the Central Social Insurance Medical Council, known as the *Chuikyo*. Usually, the price suggested by the MHLW is approved by the *Chuikyo* without any revision. However, if manufacturers do not agree with the price calculated by the MHLW, they can submit their opinion to *Chuikyo* once.

The *Chuikyo* is an advisory board for the reimbursement system relating to public healthcare insurance. This board consists of 20 individuals, 7 of whom are representatives of healthcare payers (e.g., public insurers); 7 are healthcare providers (e.g., 3 members from the Japan Medical Association (JMA)); and 6 are third parties (e.g., academics; representatives of public interest). Since payers and healthcare providers have competing interests, third-party members are required to mediate between them. The fee schedule for public healthcare insurance is revised every two years (at the beginning of even fiscal years), which is one the most important roles of the *Chuikyo*.

In Japan, the official pricing of new drugs is determined using two methods: "the similar efficacy comparison method" and "the cost calculation method" (Fig. 1). In the case of drug pricing, the similar efficacy comparison method is applied when similar drugs have been already listed in terms of efficacy and pharmacological properties. The daily price of the new drug is set at the same as that of the comparator. If a new drug is evaluated as an innovative one, the MHLW adds a premium which can range between 5% and 120% of the comparator's daily price.

The degree of innovation is judged by the following four points: (a) new action mechanism, (b) higher efficacy or safety, (c) improvement of treatment for target disease, and (d) beneficial drug formulation. The percentage of the premium depends upon the degree of innovation. If one of the four criteria is met, then the new drug can obtain a 5%–30% premium. The premium of a new drug featuring two of (a)–(c) is 35%–60%, and that of a drug with all of (a)–(c) is 70%–120%. In addition, if a new drug has a small market size or pediatric labeling, then an additional premium is paid.

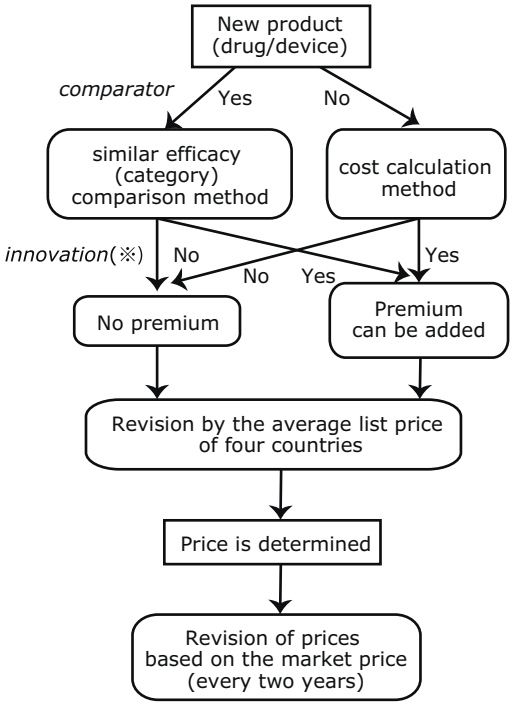

Fig. 1. Framework for pricing drugs and devices in Japan.

If there is no appropriate comparator, then the cost calculation method is used. The cost is calculated by summing the costs of manufacturing, administration, marketing, profit, and VAT. The profit rate was set at 14.6% as of FY 2016, which is the average profit rate across all industries. However, for a new innovative (or not innovative) drug, the rate is adjusted from −50% to 200% of the standard profit rate based upon the degree of innovation, safety, and efficacy compared with existing therapy.

The price arrived at, using either of these methods, may be revised by comparison with the average list price from four countries: the US, UK, France, and Germany. If the calculated price is more than 1.5 times, or less than 0.75 times, the average price abroad, this price is raised or lowered.

For example, the price of Sofosbuvir for hepatitis C was calculated based on the similar efficacy comparison method. The comparator was a combination therapy of Telaprevir, Ribavirin, and Peginterferon. Sofosbuvir is considered an innovative drug, and can attract a 100% premium. However, the calculated price of JPY 46,793.4 (USD 425.4), which represents the total price of the comparator and the premium, was less than 0.75 times the average foreign list price of JPY 92,402.9 (USD 840.0). Hence, the official price of Sofosbuvir was eventually raised to JPY 61,799.3 (USD 561.8) for a 400-mg tablet.

The price of medical devices is determined using a similar method as that used for drugs. However, the price applies to every reimbursement category (called the "similar function category") of medical devices, not each product. If a new medical device is not very innovative, the device is included in the existing category, and carries the same price as other products in that category.

In the case of innovative devices, the creation of a new reimbursement category is allowed. The price of devices included in the new category is calculated by using the "similar category com-

[1] As the definition of medical expenditure is different when considered by the MHLW and OECD, the percentages of GDP are not the same.