A Case for the Adoption of Pharmacoeconomic Guidelines in Japan

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Summary

In recent years, more and more Japanese pharmaceutical companies have been submitting pharmacoeconomic data to the government, following the official request that such data may help in setting pharmaceutical prices. The companies have cooperated because, by doing so, they could influence pricing decisions for new products. However, the quality of these data at present is considered to be poor and heavily biased.

The introduction of pharmacoeconomic guidelines that outline a set of standardised factors to be included in evaluations are necessary, so that an appropriate comparison of the cost effectiveness of the many new drugs that are introduced into the Japanese market each year can be made. In addition to supporting the development of standardised guidelines, the Ministry of Health and Welfare should clarify how pharmacoeconomic data are to be used to aid policy decisions and also mandate the publication of pharmacoeconomic data.

A standard technique for assessing the cost effectiveness of pharmaceuticals (pharmacoeconomic research) is in the process of development in many countries. In these countries there has been a decision by some pharmaceutical companies to employ pharmacoeconomic analysis in the early stage of new product development and, after the product has entered the market, many companies have presented the data collected to insurers and medical resource facilities for promotional purposes. Additionally, in recent years, pharmacoeconomic studies have been increasingly used to aid government policy decisions, such as helping to determine whether a new product should be listed and, if so, at what price. Thus, in many countries, including Australia,11 Canada12 and several members of the European Community,13 pharmacoeconomic data are already considered in the policy decision process.

In Japan, since August 1992, the need for the submission to the Ministry of Health and Welfare (MHW) of data derived from pharmacoeconomic analysis for reference usage at the time of determining the fee schedule price appears to have become recognised and, at the present time, economic data for new pharmaceutical products is submitted in virtually all cases.44 However, the way in which these economic data are reflected in the pharmaceutical pricing decision process is not clear. This article analyses the various factors which need to be examined before issuing pharmacoeconomic guidelines. In particular, Japan’s pharmaceutical pricing decision rule for new products is outlined, together with a presentation of the existing state of economic analysis in Japan and the problems faced by policy makers in determining a product’s fee schedule price.
1. Pharmaceutical Pricing of New Products

In Japan, under the universal health insurance system, reimbursement to healthcare providers is made on a fee-for-service basis within an itemised fee schedule. Included in the fee schedule are pharmaceuticals, the price of which is set by the MHW, and is revised every 2 years based on surveys of the actual price paid by the provider. These prices tend to be lower than the reimbursement price because of reductions made by wholesalers. Thus, even though new drugs may have high launch prices, these are usually reduced each time the fee schedule is revised. This gives pharmaceutical companies the incentive to continually introduce new drugs. Physicians also have an incentive to prescribe new drugs since, although the degree of price reductions may be less, the higher prices assure them a greater absolute level of profit.

Until recently, the pricing of new pharmaceutical products in Japan was quite basic. New products were priced slightly higher than an existing comparable drug. If an appropriate comparator did not exist, a price was set by a relatively simple calculation of its developmental costs. However, very few drugs had their price set based on the latter method. Pharmaceuticals which were considered to offer pioneering, utility or marketability benefits were issued with a higher reimbursement price, but these premiums were vaguely defined.

In 1992, 3 different categories of new drugs and their respective premiums were defined. The MHW seemingly went some way towards recognising that genuine innovation needs to be rewarded. For a new pharmaceutical to be classified as ‘innovative’ the development of the product must be based on an entirely new concept, it must be judged to offer a marked improvement or advancement in pharmaceutical therapeutic health-care delivery, and its safety and efficacy must be scientifically and objectively proven. The premium offered to ‘innovative’ drugs originally lay between 10 and 30%, with 20% as the standard, but from April 1996 this range was increased to between 20 and 60%, with a standard premium of 40%.

The second classification is that of ‘useful’ drugs. The requirements for this category are less stringent. Originally, the new product had to offer an improvement in efficacy over existing treatments, an improved tolerability profile, or obvious therapeutic advantages. Prior to April 1996, the premium offered to ‘useful’ drugs ranged from 1.5 to 4.5%, and had a standard premium of 3%. From April 1996 the category of ‘useful’ drugs was split into 2 subdivisions which, in this analysis, are called ‘higher level useful’ drugs and ‘lower level useful’ drugs. A ‘higher level useful’ drug has to attain at least 2 of the required conditions set for ‘innovative’ drugs, and is rewarded with a premium range of 5 to 15%, with a standard of 10%. Alternatively, to be awarded the ‘lower level useful’ drug premium range of 1.5 to 4.5% with a standard premium of 3%, the tolerability and efficacy of the new drug have to be scientifically and objectively proven, or there has to be an expectation that the new drug offers improvements in the technique of pharmaceutical manufacture which will lead to better medical treatment.

The final classification is that of ‘market compensating’ drugs. Prior to the April 1996 revisions, a new drug had to either be targeted to a small treatment population or to be entered into a therapeutic class with a small market size to be included in this category. The premium for ‘market compensating’ drugs fell within the range of 1.5 to 4.5%, with a standard premium of 3%. Now this classification has also been divided into 2 subsets, ‘higher level market compensating’ drugs and ‘lower level market compensating’ drugs. A ‘higher level market compensating’ drug has to target a population with a very rare disease, and has been given a higher premium range of 5 to 15%, with a standard of 10%. A ‘lower level market compensating’ drug

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1 Exceptions to the itemised fee-for-service form of payment are limited to the areas of long term institutional care and the ambulatory management of the elderly and children younger than 3 years old.