THEMED SECTION: DRUG POLICIES IN ASIA

New Drug Reimbursement and Pricing Policy in Taiwan

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ABSTRACT

Background: Taiwan has implemented a national health insurance system for more than 20 years now. The benefits of pharmaceutical products and new drug reimbursement scheme are determined by the Expert Advisory Meeting and the Pharmaceutical Benefit and Reimbursement Scheme (PBRS) Joint Committee in Taiwan. Objectives: To depict the pharmaceutical benefits and reimbursement scheme for new drugs and the role of health technology assessment (HTA) in drug policy in Taiwan. Methods: All data were collected from the Expert Advisory Meeting and the PBRS meeting minutes; new drug applications with HTA reports were derived from the National Health Insurance Administration Web site. Descriptive statistics were used to analyze the timeline of a new drug from application submission to reimbursement effective, the distribution of approved price, and the approval rate for a new drug with/without local pharmacoeconomic study. Results: After the second-generation national health insurance system, the timeline for a new drug from submission to reimbursement effective averages at 436 days, and that for an oncology drug reaches an average of 742 days. New drug approval rate is 67% and the effective rate (through the approval of the PBRS Joint Committee and the acceptance of the manufacturer) is 53%. The final approved price is 53.6% of the international median price and 70% of the proposed price by the manufacturer. Out of 95 HTA reports released during the period January 2011 to February 2017, 28 applications (80%) conducted an HTA with a local pharmacoeconomic study, and all (100%) received reimbursement approval. For the remaining 67 applications (70%) for which HTA was conducted without a local pharmacoeconomic analysis, 54 cases (81%) were reimbursed. Conclusions: New drug applications with local pharmacoeconomic studies are more likely to get reimbursement. Keywords: health technology assessment, National Health Insurance Administration, new drug pricing policy, Pharmaceutical Benefit and Reimbursement Scheme, reimbursement.

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Introduction

Taiwan has been implementing a compulsory, universal, single-payer national health insurance (NHI) system since 1995, with the overall coverage reaching 99.9%.[1,2] The benefit package is comprehensive, covering inpatient, outpatient, and dental services, traditional Chinese medicine, and so on. Most drugs including orphan drugs, target therapy drugs, and many expensive drugs are covered. The Drug Benefit Committee (DBC) was established in September 1995, which is responsible for evaluating applications of new drugs on their listing status, reimbursement prices, and benefit coverage. In November 2007, the Health Technology Assessment division of the Center for Drug Evaluation (HTA/CDE) supported the DBC in providing evidence of clinical effectiveness and economic studies. Before the implementation of the second-generation NHI reform in 2013, the recommendation from the DBC was, in principle, the final decision made by the governing agency—the National Health Insurance Administration (NHIA). After the implementation of the second-generation NHI reform, the Pharmaceutical Benefit and Reimbursement Scheme (PBRS) Joint Committee was established under stipulation with the purpose of encouraging participation of different stakeholders (as a joint committee comprising government officials, health professionals, manufacturers, and members of the public) in the new drug evaluation process.[1,2] As such, the PBRS Joint Committee holds the right to recommend and veto legally, replacing the DBC as the final arbiter of a new drug’s suitability to the NHI system and in the development of

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Reimbursement and Pricing

New Drugs

From January 2010 onward, new drug applications have been classified into three categories on the basis of the results of clinical studies:

1. Category 1: This involves direct comparison with the best available drugs in the market, or indirect comparison through literature reference of clinical studies, with evidence of a breakthrough and innovative product with significant improvement in clinical efficacy.

2. Category 2A: This involves direct comparison with the best available drugs in the market with evidence of moderate improvement in clinical efficacy.

3. Category 2B: This exhibits equivalent or similar clinical value to the referenced drug listed in the reimbursement scheme.

Currently, at least three members in the EAM—usually comprising physicians, with at least one pharmacist—act as the principal reviewers. When necessary, medical societies are invited to provide inputs. The content of primary review includes recommendations on the new drug classification and its comparable reference products, assessment on safety and relative efficacy, suggestions on treatment dosage and pricing scheme, discussions on whether a reimbursement criterion should be in place, and so forth. According to the principles, category 1 drugs are priced on the basis of the international median price of the A10 reference countries, which are the United States, the United Kingdom, Canada, France, Belgium, Germany, Japan, Sweden, Australia, and Switzerland, countries with industrial development. Prices of category 2 drugs, including both 2A and 2B, are capped at the median price of the A10 reference countries and follow one of the following pricing schemes on the basis of their clinical merits: the lowest price in A10 countries, international drug price ratio (the ratio between new drug and reference drug in the 10 countries), treatment-course dosage ratio (the ratio of dosage per treatment course between new drug and reference drug), and price in original country. For a combination drug, price is at 70% of the sum of each ingredient’s price (single × 70%) or is priced on the basis of the price of a single active ingredient. It is worth mentioning here that many manufacturers with new drugs deemed as category 1 drugs are willing to apply at lower than the international median price to secure their spots in the benefit scheme and shorten reviewing time.

When pricing decision is based on treatment-course dosage ratio of a reference drug, an incentive can be added with sufficient evidence provided in the following scenarios (up to 15% markup can be added for each scenario) [5]: 1) when therapeutic effectiveness of the new drug is better than that of the reference drug with objective evidence; 2) when safety of the new drug is greater than that of the reference drug with objective evidence; 3) when ease of use and convenience-related attributes of the new drug, such as longer treatment administration interval, easier drug administration methods, easier approaches of monitoring effectiveness and safety, higher stability, longer duration of effectiveness, ease in carrying product, more convenience in dispensing and usage, and safer ways of packaging, are better than those of the reference drug with objective evidence; 4) when pediatric preparations are made with therapeutic implications. Apart from the aforementioned clinical benefits, the government proposed the following measures from the policy perspectives to encourage and incentivize new drug applicants from 2009. An additional markup of up to 10% can be added when 1) applicants take the variability of local epidemiological information into consideration and conduct local clinical studies after evaluations from the Taiwan Food and Drug Administration and 2) applicants conduct a local pharmacoeconomic study after quality review of the HTA/CDE (category 1 drug is excluded from this scenario because it is already priced at the optimal A10 median price).

Let us take an actual case from the PBRS of April 2013 as an example [6]. The new drug in discussion here was an anticoagulant drug with a new active ingredient, which used another anticoagulant listed in the reimbursement scheme with a similar mechanism of actions but different active ingredient name for head-to-head comparison in its clinical study. The study then went on to demonstrate that the new drug improved moderately clinically, giving it a category 2A status, and was subsequently approved for reimbursement. The manufacturer of the new anticoagulant drug leveraged extensive data such as Taiwan local medical costs and life table, and to provide quality work tailored to the local scenario for submission, the global model in the pharmacoeconomic study was also modified accordingly. The treatment dose for the new anticoagulant was two tablets daily; compared with the reference drug with different active ingredients at NT$54 per tablet daily, the new anticoagulant was then priced at NT$27 per tablet, on the basis of the calculation method of the treatment-course dosage ratio (NTS54/tablet × 2 tablet/d) ÷ [2 tablets/d] = NT$27/tablet). Because the clinical efficacy of the new drug showed superior results compared with that of the reference drug, a markup of 15% was added, with an additional 5% markup attributed by the supplement of a sound pharmacoeconomic study, which led to the final approved price of NT$32.5 (27 × [1 + 0.15] × [1 + 0.05] = NT$32.5).

As for the selection of the reference drug in pricing decisions, the fundamental screening process is based on the Anatomical,