An Overview of New Health Technologies and Reimbursement Structures in Taiwan

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In 1995, Taiwan adopted a government administered, insurance-based national healthcare service.

The national health expenditure is estimated to be around 6.6% of GDP as of 2012.

The health insurance program is managed by the Bureau of National Health Insurance (BNHI) and covers 99% of the population.

Healthcare providers are reimbursed under the global budget system and a fee-for-service mechanism where the healthcare providers claim for services provided.

The single payer system for healthcare in Taiwan is generally characterised by:

- Good accessibility
- Comprehensive population coverage
- Short waiting times
- Relatively low costs

However, it is also considered to provide a variable quality of care and is subject to increasing financial pressures.

In 1996, the BNHI established the Drug Benefit Committee (DBC) which was responsible for making recommendations to the BNHI regarding new drug reimbursement.

On July 13, 1998, the Centre for Drug Evaluation (CDE) was established as a private not-for-profit, non-governmental organisation.

The CDE aimed to provide evidence on the value of new healthcare technologies for decision makers in Taiwan.

In December 2007, the new division of Health Technology Assessment (HTA) was officially established.

HTA provided an increased focus on comparative and cost effectiveness analyses, and the impact of new technologies on the healthcare budget.

The Bureau of Pharmaceutical Affairs, within the Department of Health, is responsible for evaluating and approving all new drugs.

- Subsequently, the reimbursement of new drugs is decided by the BNHI.

In 2013, significant changes were applied to how reimbursement decisions are made due to the implementation of the second generation of the National Health Insurance system:

- Application is submitted according to the structure specified by the National Health Insurance Administration (NHIA).
- NHIA sends the dossier to the National Institute of HTA (previously the HTA group within the CDE), which conducts an independent assessment within 42 days.
- Initial recommendations for listing and pricing are made.
- A Pharmaceutical Benefit and Price Schedule Stakeholders’ Meeting involving the NHIA and public and medical professional representatives make final decisions on the coverage and reimbursement price.

New pharmaceuticals are assessed for reimbursement based on individual drug categories:

- **Category 1 (Breakthrough innovative product):** Substantial improvement of the therapeutic value is demonstrated via head-to-head or indirect comparisons.

- **Category 2A:** Moderate improvement of the therapeutic value is demonstrated compared to current best comparator.

- **Category 2B:** Similar therapeutic value us demonstrated compared to current best comparator.

For Category 1 drugs the price is set at the median price of ten international reference countries.

A bonus 10% is added to the base price if clinical trials are conducted in Taiwan.
Pricing Methods

For Category 2 drugs the maximum price is set at the median price of 10 international reference countries.

Methods used to determine drug price include:
- Lowest price of the 10 international references countries
- The price at the original country
- International price ratio method
- Treatment-course dosage ratio method

The reimbursement price may be increased by up to:
- 10% if clinical trial conducted in Taiwan
- 10% if pharmacoeconomic study is conducted in Taiwan

Additional Price Increases for Dosage Ratio Method

In the event that pricing is based on the dosage ratio method, the therapeutic efficacy, safety and convenience of the drug may be considered to add mark-ups when calculating the reimbursement price as follows:
- Up to 15% for reduced convenience
- Up to 15% if clinical trial conducted in Taiwan
- Up to 15% if pharmacoeconomic study is conducted in Taiwan

Objective

The primary aim of this study was to:

- Investigate the reimbursements of new health technologies assessed by the NIHTA with respect to drug categorisation, pricing structure and bonus principles applied.

Particular research questions to address included:
- What categories of drugs are commonly appraised in Taiwan and how might MTA affect this?
- What are the common pricing structures used in reimbursement decisions and how are additional bonus prices being applied?
- Has there been any variations in reimbursement decisions and pricing structures in recent years?

Methodology

Assessment reports from the NIHTA were reviewed from 2011 to February 2014, and reimbursement and pricing decisions from the NHIA Stakeholders Meeting were evaluated.

For each appraisal, data was extracted for the:
- Drug category
- Pricing method
- Additional bonus pricing applied

Overview of Reimbursement Decisions (by Year)

- 71% of drugs (n=37) were approved for reimbursement
- 7 drugs (CV/Anti-coagulant Disease Chemotherapy) were approved due to low price relative to comparator
- 7 drugs (CV/Anti-coagulant Disease Chemotherapy) were approved due to high price relative to comparator

Overview of Reimbursement Decisions (by Disease Area)

- 16 therapeutics not approved due to high costs, lack of clinical evidence against relevant comparators
- 4 therapeutics not approved due to high costs, lack of clinical evidence and poor efficacy
- 3 therapeutics not approved due to high costs, lack of clinical evidence and poor efficacy and safety profiles relative to comparator

Other CV/Anti-coagulant Autoimmune Disease Cancer/Chemotherapy Hypertension Endocrine Disease Neurological Disease
Category 1 – Pricing Methods

Of the two Class 1 drugs accepted, both were priced based on the median of the 10 international reference countries

(UK, Germany, Japan, Switzerland, USA, Belgium, Australia, France, Sweden and Canada)

There were no additional bonus prices added to this class of drugs despite there being a 10% increase available for conducting trials in Taiwan.

Category 2B – Pricing Methods

Additional bonuses of 15% applied to 1 drug priced using the dosage ratio method for superior clinical efficacy.

Additional bonus applied to 2 drugs priced using the dosage ratio method for increased convenience and local economic assessment, respectively.

Summary and Conclusion

A summary of the key points are highlighted below:

- During the study period, 71% of appraised drugs were approved.
  - Treatments for cancer and autoimmune diseases were least likely to be approved, based on limited clinical efficacy (versus comparators) or the economic implications.
- Treatments with a similar therapeutic value to their comparator (Category 2B) made up over half of all appraisals (56.8%).
  - This included all drugs for hypertension and endocrine diseases, as well as 60% of chemotherapy agents.
- Treatments with an improved therapeutic value (Category 2A) made up 37.8% of approved drugs during the study duration.
  - This included half of all approved autoimmune drugs and 75% of neurological treatments.
- The incidence of breakthrough innovations was low, making up only 5.4% of appraisals (n=2).

General observations:

- Of the two Class 1 drugs accepted, both were priced based on the median of the 10 international reference countries.
- Category 1 drugs, or breakthrough innovations, made up 5.4% of the approved drugs (n=2).
- In 2003, Category 2A drugs were prescribed most often, but made up only 17.6% of approved drugs (n=14) over the entire study duration.
- During the study period, Category 2B drugs were most commonly accepted, making up over half of all approved drugs (56.8%, n=21).

Assessment of the clinical and economic evidence of new therapeutics impacted on the coverage decisions, specific pricing structures used and the bonus principles applied.