

Price Strategy Bulletin

Tough Pricing Changes in Japan

Introduction

Though not all are yet finalised in detail, after months of lobbying and debate the changes that will be enacted in Japan's pricing system from April 1, 2006 are now largely known. Reflecting the difficult financial situation facing National Health Insurance (NHI) and the strong mandate given to Prime Minister Junichiro Koizumi at last year's general election, the reforms to be pushed through by the Ministry of Health, Labor and Welfare (MHLW) are viewed as harsh by all market participants.

An overall reduction of 3.16% on the basis of total medical expenditure is designed to save Yen 239 billion (\$2 billion). This is made up of:

- 1.36% cut from healthcare providers' medical/ technical fees, including 0.6% for dispensing fees, both all-time highs
- 1.4% from the regular biennial NHI drug price reduction based on market prices
- 0.2% from an additional price reduction for 'long-listed' original brands with generics
- 0.2% from price reductions on medical devices

The total reduction in pharmaceutical prices equates to 6.7% on an NHI price basis, the highest figure since 2000.

NHI Price Revision

As has become the norm every two years, reimbursement prices in the tariff from April will be brought closer to actual market prices, squeezing the drug price margin or *yakkasa*. If the market surveys performed last autumn reveal a drug's weighted average selling price to be below the acceptable discount allowance of 2% (unchanged) of its current NHI price, this price will be cut accordingly. Individual companies have been notified of their revisions but these will not become official until around March 20. Table 1 shows the recent history of price reductions.

Table 1: NHI drug price revisions since 1988

Year	Average change in NHI prices (%)
1988	-10.2
1989	+2.4 ^a
1990	-9.2
1992	-8.1
1994	-6.6 (-7.4 ^b)
1996	-6.8 (-8.5 ^b)
1997	-4.4 ^a
1998	-9.5 (-9.7 ^b)
2000	-7.0
2002	-4.6 (-6.3 ^c)
2004	-3.8 (-4.2 ^d)

a - includes consumption tax adjustments

b - includes effect of repricing high-selling drugs

c - includes special revision of long-listed drugs and repricing

d - includes special revision of long-listed drugs

The impact of the latest revision will be variable, depending on the extent of competition within a product class. As usual, generics will be hardest hit, with branded statins, antihypertensives and anti-ulcerants expected to receive an above average reduction. No company will be spared.

Long-listed products

Original products, after expiry of the patent and re-evaluation periods, with marketed generic versions (so-called 'long-listed' brands) receive special treatment on top of the regular revision. MHLW views market price competition to brands from generics as ineffective and in the previous two revisions it has targeted these brands with special price cuts, i.e. 4%, 5% or 6%, depending on their approval date, with the penalty halved for drugs listed in the Japanese Pharmacopoeia by brand name. This time, the maximum arbitrary reduction for long-listed original brands will be increased to 8%, with those already hit by revisions in 2002 and 2004 enduring an additional one-off 2% price cut.

Industry has strongly condemned this deviation from the rule determining NHI prices based on market prices of each brand. But the situation could have been worse. Last year MHLW sought to base 2006

cuts on the weighted average market price of all preparations – original brand and generic – of the same dosage form containing the same active ingredient, thus resurrecting the idea of reference pricing – a concept first considered for Japan in 1997 but rejected two years later. This issue, and whether price revisions should take place every year and not alternate years, has now been put on the discussion agenda for the future.

High-selling products

Absent at the time of the 2004 revision, repricing of certain high-selling products will reoccur this April. Seven ingredients (9 brands) are expected to be hit (see Table 2).

Table 2: Products likely to be repriced

brand	INN	manufacturer
Aricept	donepezil	Eisai
Bebetol	ribavirin	Schering Plough
Omepral	omeprazole	AstraZeneca
Omeprazon	omeprazole	Mitsubishi
Pariet	rabeprazole	Eisai
Ransap	lansoprazole	Takeda
Ritxan	rituximab	Zenyaku
Takepron	lansoprazole	Takeda
Tamiflu	oseltamivir	Chugai

Under the repricing rule existing NHI prices can be reduced if a drug meets either of two conditions:

- sales of a product initially priced by cost calculation exceed twice the original peak forecast and on an NHI basis are greater than Yen 15 billion/year, or
- a product has new indications/dosage approved and either sales have increased greatly (as above) or the price relationship with the comparator drug has changed.

Repricing cuts, which follow a formula, are within a range of 10-25%. Alpha interferons in 2002 (-25%), goserelin in 2000 (-11.5%) and aciclovir in 1998 (-14%), represent some previous examples.

MHLW has also promised to review the way it collects market prices and sales volumes of seasonal products, and to continue to push for the abolition of traditional practices by wholesalers that result in them making delivery to customers before agreeing the sales price, as this affects the reliability of market price surveys.

New Drug Pricing

To counterbalance the cuts there is some promising news.

Up to now a particularly frustrating aspect of getting a new NHI price in Japan has been that industry could only present its case and negotiate with a middleman, the Economic Affairs Division of MHLW's Health Policy Bureau. The Drug Pricing Organisation (DPO), a body of independent experts, made the recommendations on which the decisions taken by MHLW's Medical Economics Division are based, but contact between it and applicant companies was limited to the appeals process only. It is now proposed that companies can make their points to the DPO directly, at least as far as price premiums and cost calculation methodology are concerned.

Another offsetting factor is that price premiums awarded to new products could potentially see an increase:

- for products deemed highly innovative, the range of premiums (expressed as a percentage of the comparator drug's daily price) will rise from +40-100% to +50-100%;
- products qualifying for the usefulness I premium will receive +25-40% (up from +15-30%); and
- products qualifying for the usefulness II premium will receive +5-20% (from +5-10%).

Traditionally, the main problem for industry has not been the size of the premiums themselves, but the infrequency with which these have been applied in practice at anything higher than about +3-4%. Only three new drugs have met all the innovativeness criteria since 1992, for example. This situation is unlikely to change much as there has only been a minor alteration to the wording of the qualifying criteria for the usefulness I premium. However, in addition to granting a new premium (+3-10%) for products that explicitly target usage in children, MHLW has promised to review the sliding scale it uses to allocate premiums (in inverse proportion to the drug's price).

The principle remains that drugs new to Japan are priced by the similar efficacy comparison method I (when a comparable drug already on the market is

used as a benchmark), by the similar efficacy comparison method II (when the new product is deemed to have similar properties to existing drugs tariff-listed in the previous 10 years), or by cost calculation (if a price comparator cannot be identified).

Foreign price adjustment

With the most common method, similar efficacy comparison I, premiums are additional to the price initially arrived at. But for some multinationals greater price increases than from premiums alone have resulted from the subsequent application of the foreign price adjustment rule. If a drug's initial NHI price (including any applicable premiums) is 75% or less of its average public price in France, Germany, the UK and the US, then its price for Japan may be increased, by averaging the pre-adjustment price and the average foreign price. Conversely, if the drug's initial NHI price is 150% or more of the average foreign price, the Japanese price is reduced.

From the payers' perspective, upwards foreign adjustment, which at its maximum can double Japanese prices, was both unexpected and capable of industry manipulation. Four exceptions to upwards adjustment are now proposed to prevent abuse:

- for 'me too' drugs priced by the similar efficacy comparison II method;
- when the calculated price of some presentations in Japan is more expensive than in the reference countries, while others are less expensive;
- if only the non-standard strength in Japan can be compared to strengths marketed in the reference countries; and
- when the product is only available in one of the four reference countries.

Also, if the highest price in one reference country is more than five-times higher than the lowest price in other countries, the highest price is excluded from the calculation.

Another contentious issue has been the inter-strength ratio used to calculate prices of higher strengths of the same formulation from the base price of the standard strength. This maximum ratio is now set at 0.5850 which means that if a second strength is double the standard one, its highest price is only 1.5-times higher.

Generics

The main change for generics this year is that for the first time generic substitution by the pharmacist will be possible if the doctor ticks a box on the prescription form. With doctors' low opinion of generics, this box is likely to remain empty in most cases.

There is also a plan to make generic manufacturers supply in a stable manner the full range of strengths as the original brand, and not just cherry pick the most popular ones. As well as applying to new generics, it will also be phased-in for existing lines.

Pricing rules for generic entries to the tariff are unchanged from 2004. The first copy gets the current NHI price of the original brand multiplied by a factor of 0.7. Additional generic entries receive the lowest of existing generic prices until the total exceeds 20, when later entrants receive the lowest price multiplied by a factor of 0.9.

Patient Co-payment

Continuing the policy of shifting a greater financial burden to patients, seniors will pay more for healthcare this year. From October, co-payments for those with a comparable income to the working population will rise to 30%, while others in the 70-75 age bracket will pay 20%. Salaried workers and their dependents have been required to pay 30% since 2003.

Previous increases in co-payments have tended to produce only a short-term dip in overall prescribing and little increase in usage of generics. Co-pays represent the patient's share of the total medical bill - including fees for physicians, hospitals, diagnostic tests and treatments - so the drug cost component is not especially prominent.

Implications for Strategy Development

Japan is not only the world's second largest pharmaceutical market; it is the largest to operate price controls. Knowledge of the constantly evolving, complex P&R rules and procedures is essential to success. The new opportunity offered to companies to present their pricing arguments direct to the DPO should not be ignored, though it must be well prepared for and maximum use made of the limited

time available.

Past controversies, such as Japan's relatively high drug cost ratio and the *yakkasa*, have been largely defused. The practice of pricing new drugs in relation to established therapies seems certain to remain, and companies will need to apply themselves to obtaining those elusive premiums for innovativeness and usefulness, especially now that application of the foreign price adjustment rule has been curtailed.

That most infamous characteristic of the market – regular government-mandated price cuts – combined with downwards' repricing of high-selling lines makes growth prospects very difficult. But industry is not alone in feeling the pain. The government is also putting more pressure on the demand side, in large part due to the waning power of the medical lobby. Doctors and patients – not to mention increasingly independent and larger wholesalers and pharmacies enjoying higher dispensing throughput - will in turn be putting greater pressure in varying ways on the industry.

PriceSpective is an international firm of pricing strategy experts, focused on providing strategic guidance in pricing and reimbursement to the pharmaceutical and biotechnology industries. PriceSpective has specific, practical expertise in NHI pricing in Japan, and on many other aspects of the Japanese pharmaceutical market.

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