Is the sun rising for Japanese generics?

Companies need to assess carefully their entry strategies into the Japanese generics market, as health insurance reforms and budgetary measures need time to take effect. Few companies will lose by waiting, explains Jean-Michel Peny.

The Japanese market has always been considered difficult by foreign companies for political, cultural and, more recently, economic reasons. But as the second largest pharmaceutical market – with sales of US$42 billion in 1997 – all global players are present in Japan one way or another.

The Japanese generics market is also the second largest in the world – worth US$3.4 billion – but only a handful of foreign companies have a generic activity in the 'country of the rising sun'. The current economic turmoil combined with on-going healthcare reforms designed to absorb the chronic deficit of the National Health Insurance (NHI) creates conditions for a fast-growing generics market. This may have been what prompted the recent acquisition of Cox Japan from Hoescht Marion Roussel by German generics manufacturer Hexal. Such a bold entry strategy may encourage others to take the plunge, but it is as well to do so cautiously and to appreciate that change is a slow process in Japan.

By international standards, Japanese healthcare costs are relatively low. In 1996 healthcare spending comprised only 7.3% of gross domestic product (GDP) compared with 14.1% in the US. Healthcare expenditure per capita, expressed at purchasing power parity, was US$1,581* in Japan, that is 57% and 26% less than in the US and Germany respectively in 1996.

However, the government is facing a difficult situation characterised by a combination of long-term economic recession and the continuing rise in healthcare expenditure that have generated chronic health insurance deficits. Both company-managed funds and government-managed funds have been in the red since 1995.

Illustration by Rob Wilcockson

It will take several years before generics companies can reap the benefits of Japan's healthcare reforms.

In the next three years, structural annual growth in healthcare spending should be close to 4% – half of this from natural growth (due to an ageing and growing population) and half from unavoidable factors, such as increased medical fees and innovation-related costs. At the same, economic growth is expected to be between zero and 1%.

Market drivers

To align healthcare spending with economic growth, the Japanese government must cut healthcare costs drastically. To this end, the Ministry of Health and Welfare (MHW) intends to reduce the 25% of the health budget spent on drugs to 18% – the European average – by 2001-2002.

Among the proposed measures to curb drug expenditures, six will influence the development of the generics market.

Post-marketing surveillance. Since 1994, all ethical drugs must comply with the so-called Good Post-Marketing Surveillance Practices (GPMSP) guidelines. To date, companies have not yet adhered to this. As generics are often of lower quality than the original products and manufacturers often provide insufficient safety information, the Pharmaceutical and Medical Safety Bureau (PMSB) has decided to enforce GPMSP guidelines.

This should eventually improve the image of generics within the medical community. It will also threaten companies producing low-quality generics, which could be withdrawn. Moreover, the strict implementation of GPMSP guidelines will generate additional costs that smaller generics companies may not be able to bear, benefiting the higher quality generics companies.

Reform of drug pricing system. The NHI drug price system is generally blamed

*Exchange rate used throughout US$1=¥120.76.

for the high drug to healthcare cost ratio. So the government has announced it will be replaced in the year 2000 by a drug reference pricing system – like those in place in Germany, Denmark and the Netherlands.

If, like in Germany, most original brands (93%) adjust their prices to the level of the reference price reimbursed by health insurances, then the volume of generics prescribed will not significantly increase. To maintain sales, the price of generics will have to be reduced to restore their price advantage.

Flat-sum reimbursement. Since 1992, flat-sum reimbursement programmes are being gradually introduced in larger medical institutions to replace 'fee-for-service' systems, particularly for long-stay patients or those with chronic conditions.

Under this system, physicians have a strong incentive to limit or even reduce the volume of their prescriptions per patient as well as to prescribe low-cost drugs, including generics. Hospitals choosing the flat-sum reimbursement option have seen their spending on drugs decline by 40-50%.

However, so far, the flat-sum reimbursement system has not led to a significant increase in generic prescribing, mainly because of the poor reputation of these products.

Separating prescribing and dispensing. For the past six years, the MHW has been strongly promoting 'bungyo'. This is the separation of drug prescribing and dispensing functions in hospitals and small clinics. With the current system, the more physicians prescribe the higher their dispensing fees, which represent, on average, 20% of their total annual income. Bungyo reduces the over-prescribing encouraged by dispensing fees from pharma companies.

As the number of non-dispensing physicians increases, the proportion of generics prescribed should increase slowly, based on cost-benefit considerations. The bungyo rate, that is the percentage of prescriptions filled by external pharmacies, was 27% in 1997 and is expected to reach 35% in 2001 and 50% in 2005. So its beneficial impact will not be felt until 2001-2002.

Proposals to end 'yakka-sa'. Japanese authorities are also considering eliminating up-front yakka-sa, that is the drug price gap existing between the official reimbursement tariff set by the NHI and the discounted prices at which hospitals and independent clinics purchase them.

Suppressing yakka-sa could save an additional 15% on drug spending. However, strong opposition from the powerful Japanese medical community may force the government to abandon this project. In that case, yakka-sa will not disappear overnight, but decline progressively due to bungyo expansion.

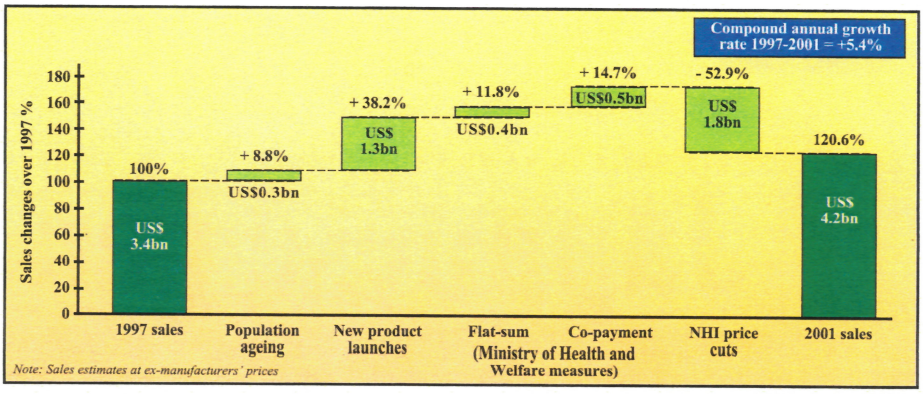

Figure 1: Sales forecasts for the Japanese generics market (1997-2001).

Yakka-sa encourages dispensing physicians to prescribe those brands with the highest discounts. So generics companies are obliged to grant physicians attractive dispensing discounts, estimated to be 25% of their NHI price (compared with 15% for original brands). This has had a disastrous impact on generics prices – between April 1994 and April 1998, generics faced an accumulated price cut of 60% compared with 25% for the overall drug market.

Co-payments. The medical co-payment for corporate salaried employees doubled in September 1997 from 10% to 20%. In addition, a new pharmaceutical co-payment has been introduced so that out-patients prescribed more than one drug will pay an extra fixed contribution that increases with the number of drugs on one prescription, for example ¥60 for four or five oral preparations. Patients aged over 70 years, must now pay ¥500 (US$4) per out-patient visit, with a cost cap of ¥2,000 (US$16.6) per month, replacing a monthly fee of ¥1,020 (US$8.4). The new co-payment system was designed to raise cost-awareness among patients and help curb over-consumption of drugs.

As a result, patients made fewer visits to physicians and the level of prescriptions, including generics, decreased. Co-payment based on the number of drugs co-prescribed should have no effects on generics development. However, the higher co-payment and increasing patient awareness in a difficult economic context will make low-cost drugs, like generics, increasingly attractive.

These measures are likely to have only a moderate impact on the development of the generic market before 2001. The flat-sum system and the co-payment increase will significantly accelerate the development of generics from 2002-2003 onwards, while bungyo expansion and yakka-sa reduction should have little impact before 2004-2005.

A gradual process

Strong opposition from influential Japanese physicians, their reluctance to prescribe generics that they perceive to be of lower quality, as well as the multiple barriers at all levels of the drug value-chain, should see the expansion of the Japanese generics market remain a gradual process.

Moreover, two powerful growth drivers for generics, that is budgetary capping of physicians' drug prescription levels and substitution rights granted to pharmacists, are currently non-existent in Japan and unlikely to be introduced in the short term.

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Joint second with Germany in the world generics market, Japan's sales are predicted to grow to US$4.2 billion by the year 2001. However, Germany's generics already comprise 20% of the total prescription market compared with Japan's 8% – although this should increase to 11% by 2001. Owing to the severe impact of NHI price cuts on generics in Japan, the 1997-2001 compound annual growth rate (CAGR) is estimated to be only 5.4% (Figure 1).

Japan has a very high number of registered generic products. In 1998, the NHI price list contains 5,046 generics brands, representing 43% of the registered brands. This explains why the average annual sales per generic is only US$0.7 million at NHI price and US$0.5 million at discounted

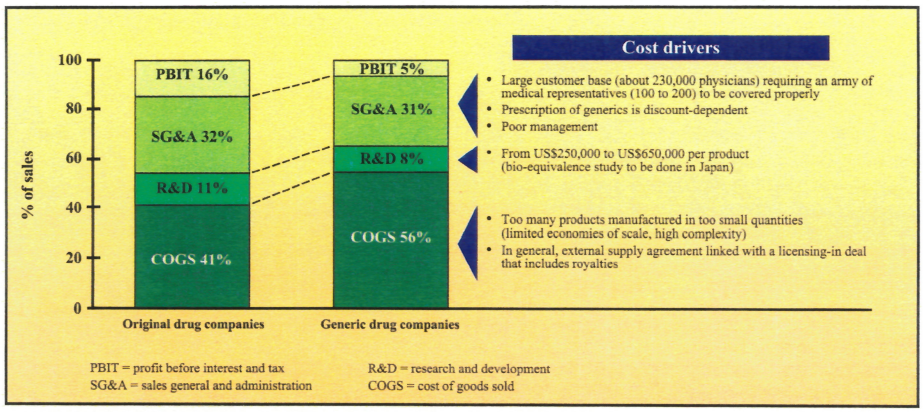

Figure 2: The average cost structure of Japanese original drug and generics companies (1997).

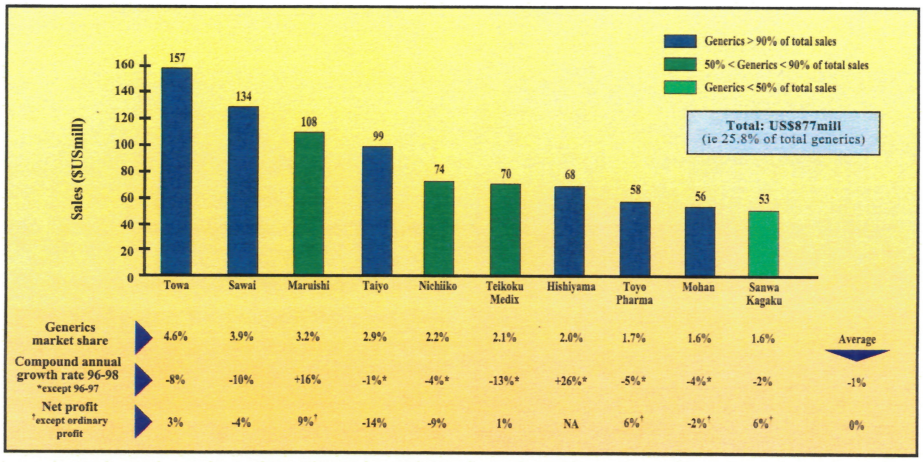

Figure 3: Performance of the leading Japanese generics companies (1997).

price. The large number of competing generics introduced for each original drug coming off-patent considerably limits the sales and profits of each generic brand. For example, 53 generics of Celect (oxatomide) and 33 of Baylotensin (nitrendipine) were introduced for the first time on the NHI price list in July 1998.

Profitability

Generics are particularly disadvantaged by the current pricing system. While the first generic copy is priced at 80% of a given original product by the NHI, successive products are either given the same price as the cheapest available generic or 90% of its price if the number of generics available exceeds 20.

These initial entry prices are then heavily discounted to secure prescriptions. As 90% of generics sales are due to physicians running small clinics, generic companies have no choice but to discount. This situation renders most generics non-profitable within two to three years, so to protect their bottom lines, companies must maintain a constant stream of new products.

These difficult market conditions explain the low level of profitability, which is further eroded over time. Generic companies' average operating margins decreased from 7.4% in 1996 to 5.1% in 1997. Compared with the German market, Japanese generics companies are on average three times less profitable. This can be explained by the:

- Current pricing system disadvantage.
- Large number of physicians (about 230,000) to be visited by an army of medical representatives.
- Large dispensing discounts needed as an incentive to prescribers.
- Poor management of the generics companies in general.
- Excessive number of products marketed (200-300 for the leaders) and sold in too small quantities (Figure 2).

Analysis of the top ten generics companies shows that only Maruishi and Hishiyama have had positive sales evolution over the past two years. Their average sales are lower than US$90 million and their average net profits are close to zero (Figure 3). The fragmentation of the generics market reflects its competitiveness – the top ten companies have a combined market share of only 26%.

Despite these poor market conditions and their unlikely improvement in the short term, some foreign companies may still be tempted to enter the Japanese generics market. There are two main options.

First, the acquisition or the joint-venture option, which has the advantage of rapid access to physicians and distribution channels, an existing product portfolio and a specific knowledge of the market. The risks of cultural clashes and high acquisition costs plus likelihood of poor profitability over the medium term represent the major drawbacks.

Foreign companies need to accept that, in Japan, downsizing is not an easy option to optimise cost structure. In addition, the poor image of local generics companies could also reflect on the purchasing company's reputation.

Alternatively, the 'stand alone' approach allows the foreign company to build a positive corporate image from scratch and keep full control of the business. The down side to this approach includes the lead time needed to develop and register generic products, the narrowness of the initial product portfolio, and the lack of specific experience and awareness in this market.

Product portfolio

Another key issue to be addressed is the product portfolio strategy. Three different options have been adopted by Japanese generics companies:

- The 'catalogue' strategy whereby companies offer a wide range of products. For example, Towa supplies 500 brands and Sawai offers 220, which cover a large number of therapeutic areas. All the leading players follow this strategy, which is valued by physicians, especially by those dispensing drugs. Thus they have a bigger choice, higher discounts and the convenience of one-stop shopping.

However, such a fragmented and diverse portfolio does not allow effective product life cycle management and leads to low or negative profitability.

- The 'disease' strategy focuses on one or two therapeutic areas. Thus Mochida and Kyoma concentrate their generics business on cardiovascular and psychiatric areas, respectively. This approach allows companies to build a strong franchise over time in selected therapeutic areas and to generate higher profits than with the 'catalogue' option. The drawbacks are the small size of some 'disease' areas and the difficulty of creating a strong franchise with generics products.
- The 'patient group' strategy covers a specific group of patients. Elmed Eisai, the generic arm of the Japanese R&D-based company Eisai, entered the generics market in 1997 by launching 12 products for elderly patients. This option

allows targeted promotional activity with a lean support organisation to generate a higher level of profitability than for the other two options. However, opportunities to focus activities on patient groups are limited.

Analysis of the generics marketed in Japan shows that most of them are conventional products, identical to the original drug. Only recently, several companies, such as Towa, Sawai, Teikoku Medix or Elmed Eisai, have launched added-value generics with the same active ingredient, but offering a convenient dosage or a more appropriate formulation. Theoretically, this is an effective product strategy to reduce fierce competition on price and prevent profit erosion.

However, in the current Japanese context, it is unlikely to work. First, NHI does not give premium reimbursement prices for value-added generics, while the development of such products costs twice as much (about US$600,000 compared with US$300,000). Second, these 'generics plus' are not valued by physicians who are more responsive to dispensing discounts than to marginal differentiations between products.

Product branding is another issue. Japanese physicians are used to prescribing drugs under their brand name. To date, only one company, Elmed Eisai, markets unbranded generics, using non-proprietary names followed by the suffix EMEC – for example, atenolol EMEC.

This approach will only become advantageous if the MHW gives pharmacists the right to substitute products. This measure is not a government priority so is unlikely to happen before 2002-2003. Thus, in the Japanese generics market, a brand name strategy appears more appropriate to generate prescriptions and develop physician loyalty.

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The Japanese generics market looks set to grow only modestly in the short term, offering only a low level of profitabily. The outlook is unlikely to improve within the next three to four years, when the cost-containment measures mentioned above should begin to have a significant positive impact.

Even so, companies with a strong strategic commitment to the generics business may decide to position themselves early in the Japanese market. This is what Hexal was doing when it acquired Cox Japan earlier this year. And it was part of Merck's thinking when it acquired Hoei, the generics division of Astra in 1997. Both deals were motivated by the desire to strengthen their global generics leadership and network.

However, experience indicates that – irrespective of the country – many companies enter generics markets too early, while few companies enter too late. Perhaps a wait-and-see strategy is the best approach for foreign companies looking for a new dawn in the Japanese generics market. SM

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