IGNORANCE IS NOT BLISS IN JAPAN

By P Reed Maurer

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A winning strategy in the Japan pharma market cannot be conceived or implemented by those who are ignorant of what moves the market. Cloning a strategy that worked elsewhere may not necessarily work in Japan, thus causing a high level of frustration for foreign company executives, writes long-time Japan pharma watcher and president of International Alliances Limited P Reed Maurer in his exclusive column for The Pharma Letter.

We could talk for a long time about cultural shock and the old adage about never the twain shall meet, but let's focus on three issues of doing business in Japan, ie, pricing, distribution, and regulatory review.

Pricing

Most of what we read about Japan's pricing policy comes from pharma industry associations. Consider for a moment the payers' view of pricing policy. Payers include the government (covers 30% of the insured), private insurance companies (who cover company employees), and patients, most of whom pay 30% out of pocket for meds and medical services.

Payers are willing to reward innovative drugs with high reimbursement prices as determined, in clinical trials, by their advantages over current (older) medicines. They believe new is better than old and should be recognized accordingly. Furthermore, once a drug is approved and given a reimbursement price there are no restrictions on its use anywhere in the country. In other words, doctors do not require prior authorization from anyone before prescribing drugs.

When pharmacists or doctors dispense drugs they are paid an out of pocket amount by the patients and receive the balance from the insurer based on the reimbursement prices. Dispensing fees are also added to provide a profit margin for the dispenser.

In theory, dispensers should pay manufacturers the reimbursement prices of drugs and make money from fees. But in practice they pay less based on negotiations with manufacturers.

To understand the real purchase price paid by the dispensers, periodic reviews of actual wholesaler selling prices are conducted. Depending on the gap between the selling price (purchase price of the dispenser) and the reimbursement price, the latter is reduced to reflect the reality of market pricing.

In short, the pricing system rewards innovations and penalizes drugs as they age and/or are discounted by the manufacturers. Payers believe the reimbursement prices of old technology should not be increased. To avoid price reductions manufacturers should not discount their selling prices to dispensers.

Distribution

All drugs in Japan are distributed by wholesalers to pharmacies then to patients. Over time fewer and fewer doctors dispensed drugs to patients. No manufacturer sells directly to pharmacies.

Why not? The answer can be given in one word – space. The space of a typical pharmacy is very limited and there are about 58,000 in Japan. This means pharmacists expect daily or twice daily deliveries because inventory space is severely limited. It is simply not cost effective for manufacturers to establish the infrastructure required to service pharmacies.

As of today, there are no dominant pharmacy chains although groups are emerging. There are hospital chains but the pharmacies in these hospitals have not formed central buying units. Every hospital pharmacy negotiates its own price with wholesalers.

There are three types of pharmacies, ie, those inside hospitals, those tied in some fashion to a doctor or group of doctors, and independent, stand-alone pharmacies. Female pharmacists account for 80 percent of the total number of pharmacists. Needless to say, pharmacists do not have much influence over the demand for drugs. This is one reason for the slow uptake of generics in Japan. Pharmacists typically will not dispense a generic unless a doctor specifically authorizes the substitution on the brand name drug prescription.

Wholesalers have evolved in many ways. First was the consolidation process which reduced the total number from about 1500 to less than 100, and among these, four control the market. Today each of the four has nationwide coverage of the market.

Another change is in their value-added functions. In the past, wholesalers simply supplied demand. Today they have qualified reps that can create demand, and it is only a small step to shifting demand, a higher value-added function. Most of their value comes from leveraging both quantitative and qualitative information.

Regulatory review

First a short history lesson. In the mid 1980s Japan's review time of NDAs was the fastest on the planet. Then scandals in the Ministry of Health slowed the review process. Meanwhile, the FDA introduced user fees, hired many more reviewers and became the fastest in terms of review time. Japan experienced what became known as a drug lag.

Furthermore, the review of new drugs is now concentrated in the Pharmaceutical Medicine and Device Agency (PMDA). People who staff this organization are eager to approve new drugs. They welcome early consultations to guide the development of a new drug through to approval. The process is transparent and guided by procedures that for the most part are in harmony with the US

and Europe. Currently regulatory review times are in line with those in the US and Europe. The drug lag is gone.

The bottom line

Key regulatory, distribution, and pricing practices in Japan work. They may not work exactly like those in the West, but they have contributed to a health care system in Japan that serves its citizens as well, and in many cases better than elsewhere. It also has adapted to meet changing needs.

It is far from a static system and must continue to evolve to serve an aging population that requires more intensive medical care. But given the history of medical care one can expect it to evolve in unique ways to provide first class medical care to everyone under a universal insurance system.