

# PHARMA

# JAPAN

A WEEKLY REPORT  
ON THE JAPANESE DRUG INDUSTRY

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## Maurer's Healthcare Insight (140)

### Where Are We Going?

P. Reed Maurer

Once upon a time Japan was predictable. Outsiders had trouble understanding Japan, but insiders knew where Japan was going. The future was an extension of the past.

The LDP would continue to be the ruling party. The yen would be stable to stronger. The Japan Medical Association (JMA) would wield the greatest political power. Reimbursement prices would be revised within a predictable range. Drug companies of all sizes did well financially. Japanese pharma companies were content to stay in their home market while establishing small outposts offshore. Foreign firms would take one step forward then half a step back.



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Yes there was uncertainty like when would a new product be approved and at what price. Like the cost of post marketing surveillance requirements. Like a change in management, particularly in foreign companies.

But the comfort of predictability was shattered in 2011. Political leadership was rudderless in the face of a major earthquake, catastrophic tsunami, nuclear disaster, and widespread closure of industries and essential services. Yet with Japan in a crisis the yen strengthened by over 5%. Along with their long time LDP friends the JMA lost its power to dictate reimbursement fee decisions. The convoy system

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of pharma companies dispersed as the small, slow ships fell behind the faster, bigger ships. The slow growth, slow drug approval home market was no longer a safe haven. Foreign firms grew faster than the market thus increasing their market share and influence.

Amid this uncertainty I dare anyone to confidently predict where we are going in 2012. Nevertheless, my own opinions follow because saying nothing is the ultimate cop out.

### Saving Money in the Healthcare System

Given the fact Japan's population is aging, and older people are more intensive users of the healthcare system, expenses are certain to increase. In 2009 expenditures per capita were ¥163,000 for persons younger than 65, but ¥687,700 for those 65 or older, 4.3 times higher. The expenses were 10.6% of national income. This percentage will escalate because healthcare expenses are growing faster than national income. The government believes the two growth rates should be balanced.

Savings can be realized but must be executed by strong leadership backed by a consensus within diverse interests. They may include:

- \* Get chronically ill elderly patients out of expensive acute care hospitals and into extended care facilities and nursing homes.

- \* Critically review the continued availability of drugs that provide no therapeutic benefit but no side effects. In other words, placebos. New drugs are regularly added to the reimbursement tariff but rarely deleted.

- \* Recommendations are made on a regular basis to remove "OTC like" drugs from reimbursement. They are unlikely to be implemented in 2012. Anyway, a shift to OTC availability will simply save insurance societies money but cost patients more money, unless the move to OTC lowers consumption.

- \* Conducting tests is a money maker for hospitals and clinics. I understand an ounce of prevention is worth a pound of cure, but the frequency of some tests is not cost effective. Ditto for doctor visits. Hard to believe but there are 230,000 people in Japan who visit the hospital 21 days or more per month, most of them elderly. An MHLW official said in a classic understatement, "Not all visits to the hospital

are necessary."

- \* A rational immunization program to prevent rather than treat diseases like measles and pneumonia.

### Generics and Long-Listed Drugs

Ever wonder why the Finance Ministry keeps pushing to lower the reimbursement prices of long-listed drugs to the generic price level? They don't talk about promoting generics. The reason is the real money to be saved is in long-listed drugs.

However, the MHLW keeps pushing back because they know long-listed drugs are the lifeline of many pharma companies. A significant lowering of prices, unlike the relatively minor 2.2% reduction in 2010, would deal a body blow to companies without new products.

But the time is coming when the need to reduce costs is greater than the need to protect certain pharma companies. Look for a high single digit or low double digit cut in 2012.

There are a bunch of proposals on the table to increase the dispensing of generics. To name a few:

- \* Increase the dispensing fee for pharmacies who dispense more than 30% of prescriptions in generics.

- \* Have patients pay the difference between a generic and brand drug if the patient selects the brand drug.

- \* Don't lower the first generic price to 60% of the brand price from 70%.

- \* Require welfare patients to take generic drugs. A common theme is to spend more money to save money. Or to shift the cost from an insurance society to a patient. This is not a win/win game.

### Premium Price Protection and Innovation

Permanent extension of price protection for drugs without generics beyond March 2012 is not going to happen, a surprise to those who assumed the "trial" period would be continued. The objections to continuation come from those who would financially benefit from resources that become available via price reductions. The industry argues this program will foster R&D. Certainly the D or development led to approval of drugs and new indications previously neglected. And there are many requests for more of the same.



The argument price protection enhances research to discover new drugs is not as convincing. There is only one foreign company doing basic research in Japan, i.e. Boehringer Ingelheim. Many others moved to China so let the Chinese give incentives for research. Japanese companies used large (mega) sums of money to buy into research technology in the US.

Japan needs to encourage research where new ideas or seeds are sown, that is in bio ventures without marketed products that benefit from price premiums. We may see more concerted efforts in this sector next year.

These initiatives along with those that expedite development of new drugs will put a big dent in the

drug lag, benefiting both the industry and patients. This is a real win/win game.

### **2012 Is Not the End Game**

As always, the evolution of the healthcare system in Japan is a high stakes, fascinating process. 2012 is shaping up as more interesting than most years. If you are here for a short or long time enjoy the ride, influence the outcomes as best you can, then operate in such a manner as to receive a fair share of the benefits.

*P. Reed Maurer does not have a crystal ball, he just talks to a lot of people.*