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A Tough Look Back at 2006

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Loyal readers of my articles in PHARMA JAPAN recognize I am an incurable optimist with regard to the opportunities and changing dynamics in the Japanese pharma market. My most depressing experiences are with companies who eschew our advice to build a presence in Japan or shun bold moves to increase their critical mass to be serious competitors.

Is this attitude on my part a sop to justify more than half a lifetime in Japan? Or perhaps I am out of touch with the reality of opportunities in other markets that demand corporate resources. "Take off your rose tinted glasses Maurer and give us a 'realistic' view of Japan," said an executive at a recent gathering.

So, what follows is a pessimistic view of events in 2006.

Market Growth

It appears the market as measured by NHI prices declined in 2006 by almost one percent. Looking at the top 40 companies, 21 had negative growth, and in the next 40, 19 had negative growth. Only 10 companies in 80 had double digit growth. As other markets show positive growth the relative standing of Japan continued a long term decline. I once had the audacity to suggest that as measured in dollars, Japan would exceed the US market. Today, North America represents over 50% of the world market while Japan is under 10%. Some say it is only a matter of time before China surpasses Japan as the world's second largest single pharma market. Will India be next in line?

Merged Companies

Much is written about the threat of newly merged Japanese companies. But, in 2006 Astellas and Dainippon Sumitomo registered negative domestic growth. Individually both Daiichi and Sankyo declined, Mitsubishi eked out a small gain while Tanabe declined, and Taisho-Toyama lost substantial ground. Would it be unfair to say these are good examples of one plus one equals less than one?

As companies merge they face real problems integrating distinct cultures, R&D objectives, excess manufacturing capacity, and deciding what to do with businesses that have nothing to do with pharmaceuticals. Early retirement offers are over subscribed which is akin to rats fleeing a sinking ship.



Mid Cap Companies

Pharma analysts suggest so-called mid cap companies face a very uncertain future because they lack new products and perpetuate the status quo which Ronald Reagan once defined as the mess we are in. Many of these companies rely on long listed products. If the government was really serious about cutting the drug bill it would reduce the reimbursement prices

of these products to their generic equivalents and dramatically alter the status quo.

Drug Approval

By now everyone in this industry must be aware of the "drug lag," not to mention the outrageous expense of conducting clinical trials in Japan. Why would an R&D head try to fight the system when trials can be done faster and at much less cost in the US, Brazil, or India? Why would a foreign company slow the pace of development elsewhere to wait for PMDA advice or patient enrollment in Japan? The answer is they don't.

We are told higher user fees and more reviewers will solve the problem. Give me a break, the MHLW (then *Koseisho*) was approving more drugs than the FDA in the 1980's with a fraction of the number of reviewers on the FDA payroll. Seems like rational behavior for executives to not conduct simultaneous development in Japan until the system is fixed.

Wholesalers

Who can make sense of a market where wholesalers cannot settle their final prices to customers 11 months after a price revision. Or where products are supplied in a "basket" so it is impossible to determine the discount or net selling price on an individual product basis, or where margins for distribution are three to four times anywhere else in the developed world. Or where ex-manufacturer prices are a bizarre combination of an invoice price and a variety of rebates that may or may not have anything to do with the quantity sold.

At last count wholesalers in Japan employed over 20,000 MSs. Can we criticize any marketing manager for asking how these people add value. Why do we need to pay for these people when our own MRs are creating demand? When this system of subsidized employment is rationalized we will take Japan seriously.

Drug Research

In 2006 some foreign companies closed their drug research activities in Japan. In a like manner some Japanese companies announced their intention to expand research outside Japan. None of the listed bioventure companies received marketing approval for a new drug. A number of companies indicated their intention to enter the generic business, essentially forfeiting the search for new drugs.

The people making these decisions are not dumb. They must believe Japan is not a source of innovation. Or are there other places in the world, read India, where you can employ smart people at much less cost than in Japan?

In Short

A pessimist sees the Japan market as declining in relative importance, or to put it bluntly, stagnating. Reimbursement prices are routinely reduced and there is a lot of talk about promoting generics but precious little attention paid to promoting innovation.

Consolidation of the pharma industry and the whole-

saler sector is not enhancing fundamental reform, that is the creation of dynamic business enterprises with new models of doing business. Meanwhile, many mid-sized companies are a drag on the system with their old products and old fashioned ways of doing business.

Innovation is lacking in research laboratories and small venture companies have not yet demonstrated they can take up the slack. Will university laboratories come to the rescue or get mired in their own outdated systems that do not reward innovators?

Early stage clinical trials are going off shore, money for basic research is going elsewhere. Japanese companies want to expand their presence in the US and Europe. Some bureaucrats and company executives worry about foreigners buying up Japanese companies under relaxed investment

regulations. The pessimists say, "Don't worry, we have better places to put our money, stock, and time."

P. Reed Maurer had a really tough time to write this doomsday scenario.

