

Maurer's Healthcare Insight (116)

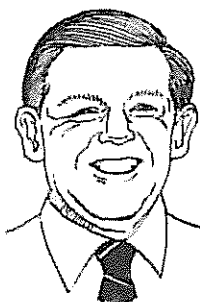
10 Questions Frequently Asked

P. Reed Maurer

Someone said a prophet has no honor in his own country. This seems to apply to me as I am more frequently asked questions about the Japan pharma market by people outside Japan than by those in Japan. Or maybe people who live here know all the answers.

Whatever the reason I spend a fair amount of time on overseas phone calls from pharma analysts, fund managers, consultants, and company managers answering a variety of questions about this market. Not complaining because there is no better mental stimulation than challenging questions from very bright people who sincerely want to know more about Japan. Having said this I must add I am paid for my time so this is not a pro bono, voluntary service.

At the risk of losing some supplemental income, I call it fun money, here are the 10 most frequently asked questions and my answers over the past few months.



are Takeda, Daiichi Sankyo, Astellas, and Eisai. These four have the largest percentage of sales outside Japan. A betting man would place his bets on these companies.

3. What type of acquisitions will Japanese companies pursue outside Japan?

First appreciate the target country for acquisitions is the US. The next priority, but of much less interest is Europe. Way down the radar screen is India then China.

Second, there are two types of targets, e.g. pipeline and market access. The first are bioventures located mainly in the US. Market access means a sales and distribution capability and the capacity to develop drugs through the approval process.

The appetite is for mid-sized companies because they are easier to digest. Money is not a big issue because the acquirers have cash and access to very low cost capital.

1. Should we license our product to a Japanese company or establish a presence in Japan to develop it ourselves?

First and foremost remember this. If you license your product out you will never ever get it back. Why? Because you will not own the product registration. I admit some products were returned but only after years of negotiations and paying obscene amounts of money.

The Golden Rule is to own your assets in Japan. You may need a co-developer, or a co-marketing partner. Fine, but make sure your name is the only name on the product registration. License out your product to South Korea, Taiwan, or Australia, but do not forfeit your presence in the second largest pharma market in the world. Yes, it will cost you money before you make money, but for this short term cost you will reap a huge return in the longer term.

If you have no intention or desire to ever be in Japan, then fine, stay out and license out. But why did you ask me the question to start with?

2. What Japanese companies will become global players?

Interesting to note that massive consolidation in the wholesale sector resulted in the "big four." Namely, Mediceo, Suzuken, Alfresa, and Toho. Recent moves in the pharma industry also created a "big four." They

4. Can we expect further consolidation in the pharma industry?

At least for now consolidation of big pharma is done. That leaves the mid and small cap pharma companies as the most likely candidates, but the process will be slow. Why? Because many are family managed, they make money, and there is no shareholder pressure for change.

Mergers among these companies are unlikely because there is an absence of synergy, i.e. one plus one will yield point five. Japanese company "outsiders" could make a move. A prime example is Kyowa Hakko Kirin.

5. What do you expect in the generic market?

Slow but steady growth, not a boom. Generics currently represent about seven percent of value in the market. Because the total market is so large a 10% value share is a real business.

The short term beneficiaries of growth will be the domestic pure play generic companies, i.e. Sawai, Towa, Nichi-Iko, and Fuji. Longer term the multinationals like Teva, Sandoz, and Mylan will capture market share because of a more favorable cost structure. Pharma companies who are entering the generic business because they have no other sources of revenue growth will be laggards. Small generic companies and *hansha* (dealers) must consolidate or come under the wings of the larger players.

6. What is the expectation for price revisions in April 2010?

The consensus for an average price reduction in 2010 is around 8%. But the average doesn't mean much. The bigger issue is what will happen to long listed drugs. If the Finance Ministry has its way there will be double digit price cuts for these drugs that have generic competition. Generics will suffer larger price reductions than the average rate because there is so much competition for market share based on discounts.

Medical fees may not be cut but not increased. Ditto for dispensing fees. The new government owes no political debt to doctors or pharmacists who long backed the LDP.

Zero price cuts for patented products is still a dream but not off the table. Think 2012.

7. What changes in health care policy can we expect from the DPJ?

More attention and more money will be given to fostering innovation in drug discovery, vaccines, diagnostics, and medical devices. Greater efforts will be made to reduce the approval lag in all these areas. Bureaucrats in the MHLW cannot protect companies that do not innovate.

Because Japan historically prides itself on equality and access to health care, efforts will be made to rectify the imbalance between the availability of quality care in rural areas versus the large cities.

8. How are foreign companies doing in Japan?

In a word, great. Not long ago no foreign affiliated company was in the top 10; now there are five. In 2008 only one of the top 10 foreign companies had

negative growth. Six of the top 10 Japanese companies had negative growth.

In general they have robust pipelines and are able to secure good people to develop and sell their products. Some of the most exciting action can be seen in foreign biotech companies who are developing products that satisfy unmet medical needs.

9. Are there any barriers to entry in the Japanese pharma market?

The only investment barrier to Japan for Western pharmaceutical companies since 1975 is their inability to make attractive acquisitions. Other issues that affect all firms, both Japanese and Western are:

- * Operating in a deflationary environment, i.e. downward price revisions every other year.

- * The high cost of clinical development in terms of both time and money.

- * The high cost of distribution.

- * A lag in the drug review process.

10. How do you see market growth in the future?

Market growth will be driven by two factors, i.e. aging of the population and innovative products for unmet medical needs.

Given these two factors we will

see both value and volume growth. Do not expect double digit growth, but healthy mid-single digit growth.

This said, it is more important to look at specific therapeutic categories. For example, high growth of drugs for cancer, low growth for antibiotics.

P. Reed Maurer may not have an answer for every question but he will have an opinion.

