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SUCCESS/FAILURE BUSINESS MODELS IN JAPAN'S PHARMA

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Nothing could be further from the truth than an assumption held by many Westerners that nothing changes in Japan, writes long time pharma industry watcher P Reed Maurer, who is president of International Alliances Limited.

"Same old same old" is often uttered by visitors who come here for three days and leave without the decisions they expected. Reality is quite different and acutely so in the pharma sector at the present time.

What follows is a personal assessment of the business models that will be successful versus those that are not sustainable during the next three to five years. Government regulation of the industry is also evolving rapidly, but space does not permit an analysis.

Success drivers

An undeniable fact in the pharma business is new products drive growth. Old technology may sell and be promoted by bill payers, but it does not excite doctors treating patients with real diseases. New technology is the result of advances in basic science, and today the frontiers of science are being pushed back at a rapid pace.

When I started in this industry 52 years ago new antibiotics were all the rage. Today, much to the chagrin of those who monitor the pulse of health care, it is difficult to find a pharma company with a new antibiotic in clinical trials. Large molecule drugs already dominate the top-ten list of worldwide sales. Chemotherapy for cancer is on its way out and immunotherapy is coming in.

Companies can insure their future success via a productive discovery research program combined with an aggressive licensing-in program. One without the other is less effective because it is nigh impossible to guarantee a regular flow of new products from either strategy alone.

30 years ago it was fashionable for companies to express an interest in every new product, irrespective of its indications. Companies now focus their research and licensing in resources on specific therapeutic areas. The result is specialization: think eye care and dermatology.

Finally, the barriers between industry and academia are breaking down. Companies that forge strong ties with university laboratories are certain to level up their research productivity.

The get-out-of Japan factor

For a long time, Japan has been a nice, comfortable market for Japanese companies. Why? Its size, one language, at times protected, and always inclined to favor innovation, thus high reimbursement prices, rapid market diffusion, and a "long tail" for old products. There was no motivation or qualified people to execute a move outside this Garden of Eden.

This attitude changed when some of the larger companies merged, and others had grown to a size where further growth in Japan was very difficult. The move outside, still evolving, is driven by new products marketed by wholly-owned subsidiaries or by acquisitions of companies with local infrastructure.

Some acquisitions were notable failures, mainly because of the lack of people who knew how to run a business outside Japan. But this is changing so we now have a reasonable number of companies with more than 50% of their revenue outside Japan.

Companies that persist in a strategy to get out of Japan will be successful, or at least their chances will be better than if they stayed in Japan. No single market can sustain perpetual growth. Think of the Swiss companies as early adopters of international expansion. US companies followed later.

Medium sized companies face serious issues

Mid-sized companies, often managed by closely held families and dependent on old products called long-listed drugs, are growing revenue by selling generics. These so-called hybrids are a mix of brand name legacy drugs and generics. The former are declining and the latter are growing albeit with lower margins, thus profit is eroding.

These companies have yet to face a going out-of-business crisis but their business models are not sustainable. The generics part of the hybrid model will certainly face pressure from the pure play generic companies with a lower cost and expense basis as reimbursement prices are forced down.

With not much new in their pipelines, some will evolve into generic companies and carve out a niche among loyal pharmacy customers. Others may be able to license in a product to stay alive while reducing expenses, surviving but with a diminished profile.

Mergers within this group will not create synergies so they are unlikely to occur. A tie up with a company with new products but less than adequate marketing muscle may be feasible. Think emerging foreign or Japanese companies.

Pharma subsidiaries of Japanese conglomerates

It was a fad for large diversified companies to establish pharma divisions. They could not resist the high profit margins of pharma. Unfortunately their research output did not sustain growth. Furthermore, their corporate cultures are not sympathetic to the long lead times of discovery and development.

Therefore, beer companies that went into the business later exited or put their pharma divisions into larger pharma companies. Think Kirin and Kyowa Hakko. One company, Ajinomoto, exited the business through an alliance with Eisai whereby it owns 49% of the resulting entity but Eisai runs the business.

Survival of others may depend on a shift to medical devices while gradually retreating from the pharma business unless they can use their access to capital to make product acquisitions.

Small generic companies

This definition includes many companies that rely on larger generic companies for contract manufacturing business. It is likely we will see consolidation in this group as there are literally scores of companies chasing a dwindling amount of business as the larger companies integrate their supply chains.

Simply put the generic business will be dominated by a handful of Japanese and foreign generic companies. Think Teva and Sawai. This process will accelerate when the generic market penetration reaches 80%, and prices are forced down by government and competition.

Conclusion

Change equals opportunity as old business relationships are less binding and the good-old-boy network is not sustainable. For those with new products this is a great time to be in Japan as opportunities abound.