GENERICS IN JAPAN

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The evolution of generics in Japan is an interesting story that says much about the differences of this market compared to the US or Europe. This article will try to capture the essence of past events, where we are now, and reasonable assumptions about future directions, writes long-time Japan pharma watcher and president of International Alliances Limited P Reed Maurer in his exclusive column for The Pharma Letter. .

From birth through adolescence

Generics and the companies who manufacture and sell them have been around for a long time but were flying under the radar. That is, their market shares did not seriously impact brand name drug sales. A major reason stems from the basic structure of how drugs are approved and reimbursed in Japan.

New drugs are listed in Japan's reimbursement tariff four times per year, generics are listed twice a year. New drug prices are typically high compared to the USA or Europe, but they are subsequently reduced, never increased. Patents are strictly enforced so exclusivity is guaranteed for at least eight years.

By the time generics enter the market original drug prices have declined so a large price umbrella does not exist as it does in the USA, where prices tend to increase over the patent life of a new drug. Furthermore, since out-of-pocket costs for patients are 30% of the drug reimbursement price, the price advantage for the generic is typically not a significant reason for switching from the brand name drug.

Nevertheless, when pressure came from the payers of health care to reduce costs the government introduced financial incentives to increase generic dispensing and set targets for generic penetration of the market represented by off-patent drugs.

But the going was slow because there are few strict formularies in Japan that can dictate or require the dispensing of generics as soon as the brand name drug loses its exclusivity. Around this time most people found it hard to believe the 80% target for generic substitution could be achieved in 2020.

We are now less than one year away from 2020 and the generic market share is reported to be in the 77% range, thus belying the unbelievers and, baring some unforeseen development, the 80% target will be achieved.

Because of the way the price system works, and the introduction of financial incentives to promote generics, savings in the health care system have not been as dramatic as originally promised. And this has not escaped the notice of Finance Ministry people who were originally skeptical about the focus on generics as a way to reduce costs.

They are well aware that the real money to be saved had to come from lowering the reimbursement prices of off-patent brand name drugs to the generic price level. This action was resisted by the Ministry of Health because they knew such action would have a severe effect on the many companies with significant sales tied to so called long-listed drugs. In other words, companies that have not launched new drugs that would move them up the price curve.

As an aside, we should note the Ministry of Health has an obligation to promote a viable, innovative pharma industry. This is a unique mission among regulatory bodies. The Ministry therefore encouraged brand-name companies to focus their R&D activities in specific therapeutic areas to develop and launch new drugs. Few took this advice.

But about four years ago the Health Ministry bowed to Finance Ministry pressure because much of the industry was hooked on their legacy products. So now we are seeing serious moves to reduce drug reimbursement prices every year instead of every two years, and to reduce long listed drug prices down to the generic level.

Losers and survivors

The generic space is currently made up of two types of players, ie, the pure play generic companies, both Japanese and foreign, and brand-name companies who moved into generics to generate much needed revenue. The latter did enjoy revenue growth, but profit lagged. Given the coming pressure on margins, it is hard to see how these companies can sustain themselves because their cost structures and product offerings are not in the same league as the pure generic companies.

Which brings us to the point of classifying generic companies into two types, ie, those with a low-cost basis derived from production of their raw materials outside Japan, and those with high costs because their operations are confined to Japan.

It is hard to see how the latter will compete and sustain their growth. A possible strategy will be to focus on quality in terms of product presentations and packaging. This may help them succeed against those who only focus on lowering costs to the detriment of quality that Japanese consumers expect.

The dark horse in this race to the top of generic competition may very well be biosimilars. Those launched to date captured the majority share among all generics. As these products are exact replicas of the original drugs, they avoid questions of quality by patients and pharmacists.

What to look for next

Presently everyone will agree there are too many generic manufacturers. Entry barriers did not exist, and money was to be made as the switch to generics gathered steam. It is surprise-free to forecast a shake-out as the industry consolidates. The smallest players concentrated on the West Coast of Japan may become captive suppliers to larger companies.

Companies like Sawai, Nichi-Iko, Mylan, Teva and Sandoz will dominate the field. But the days of double-digit growth will disappear as the 80% penetration target is achieved, financial incentives are removed, and fewer drugs go off patent.

Some of the brand-name companies that ventured into generics will become pure play generic companies. Two examples are Meiji and Nippon Chemiphar. Others will exit the generic business as Eisai did by turning over its generic business to Nichi-Iko.

Generics are currently priced at different levels depending on when and how many of the same ingredients were listed in the reimbursement tariff. It is the governments' intent to convert to a single price system in 2020. This action is certain to accelerate the changes mentioned above.

Looking ahead it would be a mistake to believe the Japanese generic market will evolve to look like the US or European markets. A wiser strategy is to understand the market for what it is and compete in it with extraordinary efforts. Japan is never easy, but the payoff for success is much better than most everywhere else.