

Maurer's Healthcare Insight (137)

Negatives of the Japan Pharma Market

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Loyal readers know I am an avid optimist and proponent of the Japanese healthcare system, its pharma market, and the opportunities for foreign companies. But lest I be accused of wearing rose colored glasses while eating too much rice, I hasten to point out some real problems in this system.

This is not to say you should keep an open airline ticket for travel out of Japan so at the first sign of illness you can fly "home". My experience suggests you should take advantage of the health care available in your backyard. Four of my five children were born in Japan, I had six surgical procedures in three different hospitals, all with favorable outcomes; and members of my family received effective emergency care on numerous occasions.

But health care systems anywhere in the world are not perfect. There is always room for improvement. Hence my modest attempt to point out shortcomings in Japan.

The Bridge from Idea to Drug

Years ago Japan joined the US and Europe as a source of new drugs. The rest of the world does not matter in this league. In 2010 eight of the top 50 global drugs originated from Japan.

The genesis of a marketed drug begins with an idea followed by a torturous, time consuming, and expensive development process. To say this is a risky business is an understatement well understood by readers of PHARMA JAPAN.

Ideas, like seeds, need a fertile ground in which to grow. They need to be nurtured through preclinical and clinical trials to demonstrate safety, efficacy, and more recently cost effectiveness. Japan has and will continue to generate seeds; the problem is an inadequate infrastructure or bridge to take ideas forward in the laboratory and clinic.

One such bridge is a viable, innovative, and dynamic bioventure industry. Something like 1,600 bioventures were formed in Japan during the past decade. Unfortunately most are not prospering. Why? Primarily because of the lack of funding and government support.

In a nutshell, venture capital in Japan is very risk averse, thus reluctant to invest in early stages of seed development. Going public is not an option until the



bioventure has an approved drug. Private investors closed their wallets after they lost their shirts on investments in the few bioventures that did go public.

Government support is not focused in one ministry, hence the impact pales in comparison to an NIH in the US. Clinical trials are expensive in Japan and patient entry into trials is slow. It is not surprising that a majority of early (Phase I) clinical trials of Japanese origin drugs are begun outside Japan.

As Chairman of a bioventure I could go on with a litany of woes, but suffice it to say that a bridge must be built and the soil made fertile or Japan will miss out on a growing, vibrant industry.

Treatment of Mental Illness

Japan's 1,076 psychiatric hospitals have a 90% occupancy rate in 13.5 times more beds per 100,000 people than in the US. Patients admitted to these hospitals are hospitalized for 307 days on average, compared to just over one week in the US.

The obvious conclusion is Japanese mental patients are not treated and reintegrated into society. Rather, they are isolated from society, out of sight and out of mind. Too often treatment is sedation to keep patients manageable.

As this population continues to age at a historically unprecedented rate, the number of aged dementia patients will increase. If they too are essentially locked up the problem is only going to get worse.

Psychiatric drugs in Japan are not big sellers. For example, the market for schizophrenia drugs in 2009 was ¥123 billion. The gastric ulcer drug market was ¥250 billion. The stomach is better cared for than the head.

Care for the Elderly

When I came to Japan in 1970 only 7.1% of a population of 104.7 million was 65 years or older. In 2010, 23.2% of 128.1 million people were 65 years or older. In 1970 care for the elderly was not an issue. In fact, through the mid 1990's there were no long term care hospitals or beds. By 2009 there were 5,646 hospitals and clinics with 352,749 beds, and a per bed utilization rate of 91.2%. Not surprising the available beds are full because there is only one bed for 84 people 65 years or older.

In short, this health care system was built to care for a younger population with acute diseases, and has not yet adapted to an elderly population with chronic diseases. Some progress is being made, but the current situation does not embody the respect and veneration this society has traditionally held for the elderly.

Vaccines, Narcotics, and Blood Products

These products are closely controlled by the government either directly or indirectly. In other words, people in the business do not face market competition from inside or outside Japan. This results in the following:

- * New vaccines are not discovered in Japan.
- * Vaccine innovation is nonexistent.
- * Treatment of pain is still in the dark ages.
- * New medications for pain are not discovered in Japan.
- * A goal of self sufficiency in blood products is totally unrealistic yet ritually reaffirmed.



* Outsiders and their innovations are not welcome.

It remains a mystery how this country can be a leader in a wide range of high technology fields yet remain so backward in vaccines, pain management, and blood products.

The Common Thread

A commonality in the above mentioned negatives is the issue of change. Bioventures did not exist in Japan 10 years ago. Mental illness can no longer be ignored as though it does not exist. The elderly are now all around us. Flu vaccine is not the only vaccine on the planet. Pain can be controlled versus endured.

Change is tough to accept so I am not optimistic Japan will solve these problems. Hopefully a new generation of MHLW officials,

company executives, and doctors will prove me wrong.

P. Reed Maurer only criticizes those he likes because those he does not like are not important.

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後発医薬品調剤体制加算 : Premiums for generics dispensing systems 後発医薬品使用体制加算 : Premiums for generics use systems

The Japanese government has introduced premiums for generics dispensing systems (後発医薬品調剤体制加算) for dispensing pharmacies and premiums for generics use systems (後発医薬品使用体制加算) for medical institutions as part of its efforts to promote the use of generics.

Pharmacies are allowed to claim premiums for generics dispensing systems of six, 13 and 17 points (one point = ¥10), respectively, if generics they dispense account for 20-25%, 25-30%, and $\geq 30\%$ of all drugs they dispense (other than enteral elemental dietary products (経腸成分栄養剤) and special infant formulas (特殊調製粉乳) classified as drugs) on a volume basis. In order to be eligible, pharmacies are also required to post in and outside their facilities that they are promoting the use of generics and claim premiums for generics dispensing systems.

Medical institutions are eligible to claim a premium for generics use systems (30 points or ¥300) for inpatients treated under a fee-for-service system (出来高払) if the number of generics included in their formulary (病院医薬品集) accounts for at least 20% of the total number of drugs in their formulary (採用品目).