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# Japan Pharma Industry Reform

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The Japanese pharma industry has a long history of undergoing transformations or reforms. As I will elaborate below, the pace of reform accelerated after World War II and is now in a period of critical restructuring.

First the history. The chart below is a snapshot of Japan's oldest companies. They were all founded in Osaka on one street called Doshomachi Dori.



### 1975-1990

In 1975 restrictions on foreign ownership ended and Japanese companies transformed themselves into research and development companies (R&D). The research output were small step innovations with high reimbursement prices. During this 15 year phase most of Japan's internationally competitive drugs were discovered.

Company	Year founded	Founder
Tanabe	1678	Gohei Tanabe I
Ono	1717	Ichibei Ono I
Takeda	1781	Chobei Takeda I
Shionogi	1808	Kichibei Shiono
Fujisawa	1894	Tomokichi Fujisawa I

All five companies started as wholesalers of herbal medicines, many imported from China. In the late 19th century they began to import Western drugs which were distributed throughout Japan. In the early 20th century they began the transformation from wholesalers to manufacturers.

During this long "incubation" period the founders and their successors demonstrated entrepreneurial ability. Followers like Yamanouchi, Eisai, Kissei, Kyorin, Mochida, Santen, Taisho, and Banyu were likewise founded by individuals who took risks to establish their businesses.

By 1950 they were capable of manufacturing basic drugs like sulfa, penicillin, amino acids, vitamins, gastrointestinals, and various chemicals.

### 1950-1975

The next phase was much shorter, lasting 25 years. Although some companies conducted basic research, their prime focus was on licensing in drugs from Western companies who could not establish wholly owned entities in Japan. The only route of entry was through a JV. This gave Japanese firms the chance to build on their manufacturing base and establish development functions that worked closely with regulatory authorities. They completed the transformation from wholesalers to development and marketing companies (D&M).

### 1990-2000

The old JVs were practically all dissolved by 1990 and research was refocused on first generation drugs. Resources were shifted from non-core operations like foods, chemicals, animal health and OTC products. Most of these businesses were divested and alliances were formed with newly emerging companies in the West who had no presence in Japan.

### 2000-2005

Consolidation among large cap pharma companies began and moves out of Japan to the US took off as market growth slowed in Japan to low single digit rates. Innovations outside Japan were acquired rather than licensed in. Efforts to focus resources moved to sales force realignment and therapeutic specialties.

### Future Reforms

#### I. Mid and Small Cap Companies

With some exceptions middle and small sized companies have not transformed themselves into research based companies or successful players in niche markets. They owe their existence to long listed, off patent drugs that enjoy relatively high reimbursement prices. Or to drugs that are no more effective than placebos but are profitable.

These firms do not go bankrupt so there is no creative destruction. Kind of a slow but painless drift into obscurity. Hard to imagine the big, reformed firms will "rescue" these companies. It would only impede their overseas expansion and use up resources that are required to buy innovative drugs.

A tough love approach is to reduce the prices of off patent drugs to the level of generics, and delist drugs that show little efficacy. These actions would save the health care system huge sums of money that

could be channeled into fostering innovation in bioventure firms who are starving because of inadequate financing.

## II. Bioventure Companies

As just mentioned, the seeds of innovation arising from Japan's institutions and individuals do not have a fertile ground to blossom and bear fruit. A fertile ground includes a dynamic IPO market, venture capital financing, quick regulatory review, and a cost efficient infrastructure of clinical trial centers.

Japan's public and private sector has always fostered innovation, i.e. take the best the world has to offer and make it better. Old technology was never encouraged in any industrial sector. As pointed out above resources exist if reallocated. Brains and ideas exist but are left to wither. Reforms are urgently required to stop backing losers and reward potential winners.

## III. Generic Companies

Generic companies and a generic market are relatively new to Japan. Growth of both has been rapid, albeit from a low base.

This is a very different business from the pharma business in all respects. Cost of goods sold must be lower; manufacturing must be leaner and more flexible; and the development model involves far fewer parameters. All of these are not yet optimized in Japan.

But most in need of reform is the marketing and sales model. Margins in the traditional wholesaler channels are too high; MRs are too expensive; and financial incentives to use generics defeats the purpose of saving money.

What more information does a doctor need about the generic equivalent of a 10 to 15 year old drug? Is the MHLW approving generic drugs of inferior qual-

ity? Are pharmacists so busy they do not have time to talk to patients about generics?

Consolidation is urgently required so the surviving companies will be respected players in the market. Distribution costs must be slashed while small dealers are eliminated to ensure consistency and reliability of supply.

## IV. Acquisitions Inside vs. Outside Japan

Executives of Japanese companies who make acquisitions in the US are portrayed in the media as heroes. Foreign executives who make acquisitions in

Japan are considered akin to rapists. Something is wrong with this picture.

Reform of the mid and small cap companies could be expedited through their acquisition by foreign companies who want to ramp up their presence in Japan. Ditto for the plethora of small generic companies. Bioventure companies would benefit from foreign investment if it was encouraged.

## V. Vaccine Companies

To say that vaccine companies in Japan are in need of reform is an oxymoron. No innovations. Not enough capacity to respond in a timely manner to a new flu virus. No protection from measles epidemics that close schools.

I could go on and on but suffice it to say this is an example of mismanagement by bureaucrats in the name of self sufficiency. Japan should be ashamed of its policies that stifle innovation at home and the barriers that are erected to keep out innovative vaccines from abroad.

*P. Reed Maurer knows reform takes place in Japan but wishes it would go faster.*

