

## Pharma's Hot Issues under the Microscope

**Philip Carrigan**  
**Partner, Optia Partners**  
**philip@optiapartners.com**

“The Japanese Pharma industry may not be able to survive unless appropriate measures are taken,” said the top company director.

“Some companies may struggle to become global players, and others may only focus on niche areas. Small or midsized companies that rely on old products will be required to either launch new products or change their cost structure so that they can survive as a generic company. Mergers and acquisitions with global megapharmas may be beneficial, as the case of Chugai indicates.”

I asked 100 managers and directors working at the leading Japanese and foreign Pharma companies about the major issues facing the industry and the above comment was just one insightful response.

More than 30% of these decision makers listed generic drugs, government intervention and National Health Insurance (NHI) issues on top of their list.

Approximately 21% of respondents believed Japan's clinical study environment was a significant issue and the growth of global companies in Japan with a strong pipeline of products was the key issue of more than 19% of interviewees.

Surprisingly, just 7% of the 100 executives stated that M&A's were the major point within the Japanese Pharma industry.

\* The following are more comments made by the key decision makers.

### **NHI Reductions & Generics**

\* Because of the price cuts and growing use of generic drugs, Japan is no longer profitable for everyone; only companies that develop innovative new drugs could succeed.

\* NHI price reduction every 2 years

\* Price pressure and less transparent approval procedure by MHLW

\* The government tries to suppress medical cost.

\* Price pressure and less transparent approval procedure by MHLW

\* Health insurance system here is no longer very comfortable for us, compared with the past system, which included 100% coverage. Currently we need to pay 30% of total expense each time when we see doctor

and this ratio is expected to be increased in the future.

\* Price cut by the government and threat from generic product

\* The biggest issue, or threat, is the continued cost containment initiatives by the health authority via biannual price cut, encouragement of generic usage, etc. At the moment, generic products have limited market share in Japan, but I fear they will suddenly be boosted at some point in the near future, when big players, such

as Sandoz, Teva starts operations in Japan in earnest, or if mergers among Japanese generic manufactures occur.

\* Generic issue. It seems generic in Japan is getting into second phase. One big impact is the change in prescription format that make it easier for doctor to allow the use of generic. The other is that MHLW has been trying to persuade Japanese mid to big Pharma change into generic company.

\* Although MHLW promotes the use of generic, on the other hand, it thinks current generic companies are weak. Until recently, it was using generics mainly to drive the NHI price down.

\* Fiscal deficit of healthcare insurance system, which will lead to lower drug price and promotion of generics

\* Nation-wide pressure to use more generic products than it used to be.

\* Further expansion of the generics market will be witnessed in the early part of this year as a result of the government's pro-generic policies.

\* Coming national health care budget shortage (Pharmaco-economic approach would be inevitable and Japanese society is not familiar with this.) Safety/efficacy issues to be more globally affected.

### **Clinical Studies**

\* Unfavorable pharma industry-related educational environment in universities and consequent lack of high-quality researchers, spill-over technologies from universities, much fewer venture companies and less groundbreaking research

\* Lack of budget and less effort to develop new compounds for unmet medical needs... Strict filing regulation of MHLW...

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- \* Bad clinical study environment.
- \* Difficulty in launching new compounds. Major portion of R&D sites (investigators) are not well qualified for clinical trials and are especially poor in CNS field.
- \* The way clinical trials are conducted and how companies operate and are structured does not meet global standards.
- \* We need a global development strategy that includes an outsourcing strategy.
- \* Japanese clinical development and regulatory environment is tough, with high costs, slow recruitment, and poor quality. You must be aware that some of the global blockbusters will never be launched in Japan because of regulatory failure. It seems clear that even the Japanese regulatory agency is recommending global development.
- \* We need improvement of productivity, cost (include clinical trial cost) and speed.

### **Global Competition**

- \* Global companies can bring large resources to make evidence for their drugs because they can expect sales in global market. Japanese companies who have sales forces only in Japan can only devote small resources to make evidence.
- \* Deregulation and subsequent invasion of Western mega pharma
- \* Globalization and M&A are the major issues.
- \* Growth of Global Pharma with their pipelines already approved outside of Japan. No growth of Japanese Pharma market. Conservative stance of Japanese regulatory.
- \* Domestic environment does not accept to remain as domestic players anymore but most of Japanese Pharma's do not have capacity to become global player
- \* There are very few companies, which have enough skills to create and develop novel mechanism compounds, such as antibodies. We (Japanese companies) are quite behind in the areas compared with multinational companies.
- \* Most of Japanese Pharma companies do not possess competitive advantages to US or European "Pharma giants" because many Japanese pharma companies have been trying to license-in something from these giants.
- \* Because of current global M&A trend for past several years, Japanese pharmaceutical companies can hardly compete with foreign companies especially when we consider Mega Pharma's heavy investments for R&D. As a result, it seems to be very difficult for Japanese companies to develop in-house original compounds by themselves.
- \* Development of a global product pipe line. The Japanese domestic market has been shrinking and the expanding global share is most critical issue. World-wide competition is good and prompts Japanese companies to develop promising products.

- \* Higher competition for local Japanese manufacturers because of increased investment and total revamp of multi-national mega pharma companies in Japan. We knew it was coming but the decision makers in the Japanese pharma did not make the move, either to step up to compete with mega-pharmas or to niche itself to certain therapeutic area, until it was too late.
- \* Being global is important. The progress in implementation of the ICH guidelines favor a synergistic, global development process, which will be primarily led by US development. Most of the Japanese companies do not have global development and regulatory expertise, which means either that they will need to license out to US companies, or develop only in Japan.

### **Drug Development**

- \* Unfavorable Pharma-industry-related educational environment in universities and consequent lack of high-quality researchers, spill-over technologies from universities, much fewer venture companies, and less groundbreaking research
- \* Management product portfolio, development new drugs, considering generic drug erosion.
- \* One of the major issues is improving the approval procedure for new products. We are struggling to get approval for our new products even with good enough submission data.
- \* The pipeline is not substantial. R&D capability and marketability are weak. → poor globalization correspondence to a change of an insurance regimen is bad.
- \* Japanese companies don't have enough pipelines and that is why their R&D costs are less than foreign companies. They don't have marketing knowledge and believe in their own experience and sales power.

### **M&A**

- \* Most of the Japanese pharma executives have worked in isolation, Japan only Pharma world for a long time, and could not act as quickly and aggressively as their mega-Pharma counterparts. In addition, most of the Japanese pharma companies still have bureaucratic and seniority-based corporate cultures, as well as many of the Japanese investigators and key opinion leaders who lead the clinical development. This leads all decisions in a conservative, risk averse direction. This could partly explain why M&A was not occurring as significantly as it is in the western world, and despite the mega mergers of Daichi-Sankyo and Yamanouchi-Fujisawa, the size and capability of these companies are still far cry from global mega-pharmas.
- \* Japanese pharmaceutical companies are anxious about M&A from multinationals because of their cheap share prices. For example, although the share price of Takeda, which is a leading company in Japan is ¥6,000, Abbott will be able to buy it easily.