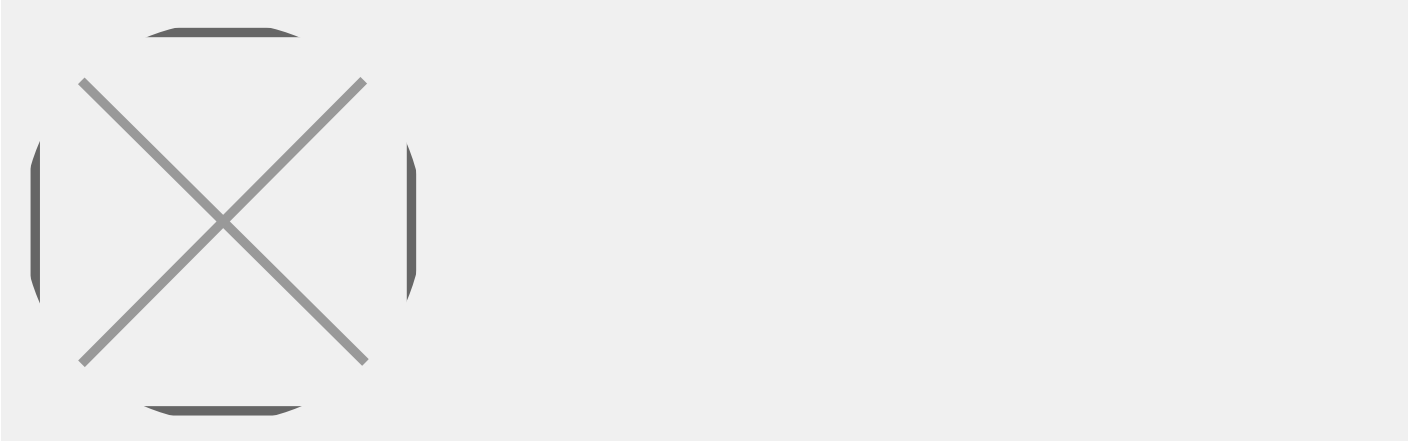
Interview: Mark Yang, Country Manager, Hospira Taiwan



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In 2010, you began your last interview with us by mentioning two things: that because of the nature of this affiliate's portfolio—with only 35% of revenues generated by pharma at the time—Hospira's strategy in Taiwan was a bit different than it was elsewhere in the world. You also said that coming regulatory change should make the pharma business much more interesting for you. Reflecting on those points in 2013, what can you tell us?

Since 2010, the Bureau of National Health Insurance (BNHI) has announced new initiatives to encourage generic suppliers, both domestic and foreign. Today, if generic companies can demonstrate global-standard manufacturing quality—i.e., PIC/S GMP compliance—then they will be awarded premium pricing in Taiwan.

This is not just talk. The BNHI means business, and has followed through on its promise: one of our own molecules now enjoys premium pricing, after its manufacturing site was granted PIQ/S GMP certification. Our team is currently preparing the ground for further molecule launches that can take advantage of these benefits.

An initiative like this is beneficial not only for companies, but also for the market, because it increases the quality level of generic products available to the patient population. At the same time, for local generic players, the call for better standards better positions them to export their products internationally.

However, even with positive change in the marketplace, the environment for generics companies in Taiwan still presents its challenges. To bring a product to market, we begin with an application for market authorization. Once we receive the authorization, we are eligible to distribute the drug—but the story doesn't end there! There is still a long way to go to full commercialization. We have to communicate with various tendering bodies. In Hong Kong, all tenders are managed through a central hospital authority—in Taiwan, the situation is quite different. The government provides each reimbursed item with a tag price, and then it is up to the company to go out and bid against other players through an assortment of tendering systems. There are, altogether, eight major tendering systems, representing the majority of key hospitals.

Prior to the tender process, the hospitals will ask for a clinical trial, and a generics company will have to conduct this trial head-to-head against the originator, chemical name versus chemical name. If the relevant committee finds that the outcome of the trial is satisfactory, they will nominate the sponsoring company for listing in the hospital. Then, a bidding tender takes place between the generic company and the originator—and if the originator is willing to drop their price, the generic company will have less of a chance to win. If the originator is unwilling to drop their price, and the generic company is, only then will the generic player have the opportunity to commercialize the drug.

Surely price is not the only factor—what about reliability of supply and other competitive advantages?

These other factors are certainly important as well. Although I must say that price is king, reliability of supply and the reputation one builds through key accounts is significant. If a generic company in Taiwan can successfully list their product with one

or two top-notch accounts, and secure a certain timeframe of prescription in those accounts, than with those invoices, and with that track record, it will be able to penetrate further into the marketplace. That is the game plan.

So, again: for generic companies like Hospira, market authorization is just the first step in Taiwan. The market favors originators. In the absence of further pro-generic policies in this country, innovators will continue to enjoy a much longer product life cycle than they do in the U.S. and other Western markets.

Does the majority of your business, then, continue to come from medical devices?

It does. As in 2010, medical devices represent approximately 70% of our portfolio by value.

In this niche, we have been quite active. We have kicked off a number of ‘blue ocean’ projects in our Medication Management System (MMS) business, and introduced several new consumables to the market. At the same time, we have recently tried to echo what the government is emphasizing: needle-free technologies, which are beneficial for patients and safer for medical professionals.

Is the medical device business more or less attractive in Taiwan than it was in the past? Something we are seeing around the world—and one of the reasons that Focus Reports is increasingly focusing on medtech in our reports—is that medtech markets are beginning to experience the downward price pressure, and the regulatory barriers, once reserved for pharma markets. We often see a picture of what pharma went through five or ten years ago!

Pharma has its challenges for us, but is becoming increasingly attractive. Medtech, on the other hand, is increasingly a threatened business. For one, a major price cut came at the end of 2011 that proved a big hit for all suppliers in Taiwan—and this cut is only the first wave. As you correctly pointed out, pharma prices have faced downward pressure for a number of years, whereas medtech was relatively untouched by the

healthcare system. That scenario is changing.

You are right, as well, about regulatory hurdles: in order to make it to the market today, medtech companies have to really demonstrate innovation, and cost-effectiveness. Only then will the assessment committee grant you market approval in Taiwan. The barriers to entry are rising.

In 2010, Hospira was generating 18Mn USD per year in Taiwan. Have your revenues grown?

Because of the price cuts we've faced in pharma and medtech, our revenues have stagnated a bit, and are still in the 18Mn USD range. However, compared to many of our Big Pharma competitors, we have done quite well—because they are shrinking. Many blockbuster molecules have seen price cuts of 20-30%. Our position, on the other hand, is relatively secure.

For the past three years, rather than focus on our top line, I have sought to improve our profit margins. We have been very successful in this sense. For instance, we have managed to create a second life cycle for one of our medtech business lines: a pain-focused MMS. We introduced a new platform, revitalized the business, and significantly improved margins.

On May 1st, Hospira unveiled the details of its new Global Device Strategy. The company reported, "Actions will include investments in retirement and replacement programs, future product releases and quality systems." What can you tell us about this strategy, and what does it mean for you in Taiwan?

Take our two major MMS platforms: large-volume infusion, and the GemStar Patient-Controlled Analgesia (PCA) line. Hospira decided, at the corporate level, to retire the older generation of the former platform—moving on to something better that we call Plum A+—as well as retire the GemStar platform, and move to the Sapphire line. Hospira saw that it needed to revisit its MMS approach, and introduce more advanced solutions to the market.

We are following suit in Taiwan, and it is quite exciting for us!

Moody's Investors Service placed Hospira Inc.'s 'Baa3' long-term debt rating under review for possible downgrade on May 22nd, noting concerns that "the drug and medical device maker's performance over the next few years remains uncertain as a result of costs related to its new product strategy and possible regulatory issues." In your personal opinion, is this a fair analysis?

As our CEO Michael Ball commented, Hospira is working to repair our foundation as an organization. We are doing so by addressing the regulatory issues you mentioned, and by migrating to more advanced platforms.

I believe that, whenever a company wants to create a better foundation for itself, there are always some painful exercises involved. Nonetheless, we absolutely believe that we are on a healthy journey. We believe that once we get there, all of the other pieces of the puzzle will fall into place for our business.

What about biosimilars? Hospira recently celebrated five years of biosimilar success in Europe and Australia. Is the Taiwanese market attractive for these products?

Hospira has been contemplating the introduction of biosimilars around Asia, and has assessed the potential of a number of markets in this region. In Taiwan, the regulatory pathway is still unclear. The industry is asking itself: what's here? The prospects are becoming clearer, but we still have to look at indications case-by-case to decide if we should attempt to market a biosimilar.

As a generic manufacturer and supplier, we look for the regulatory body to allow us a 'sample introduction' of a biosimilar or generic molecule—saving time on regulatory hurdles such as inspection and review, and possibly saving clinical trial cost. Otherwise, if the product is positioned as a new chemical entity (NCE), we would need a great amount of resources to introduce it—just as innovators like GSK or MSD require great resources when they are launching an innovative drug. We view that kind of

positioning as unattractive, and we believe it should not be necessary for a biosimilar.

Ultimately, the regulatory pathway for these products in Asia is still much tougher than it is in Europe or Australia. As such, we have not yet launched any biosimilars in Taiwan. But we are investing, we are watching the development of the market, and we are in close contact with the officers of the Taiwan Food & Drug Administration (TFDA)—holding discussions, as I mentioned, on a case-by-case basis.

A wait-and-see strategy.

Exactly.

I believe that the biosimilar space, for a company like Hospira, is well worth our time and effort. If we can find a way into Asian markets, it would be very rewarding for us—particularly because the majority of the local competitors we might come across in Asia have not yet developed the skillset to enter the biosimilar filed. The distance between these manufacturers and achieving biosimilar production is a crucial space for multinational companies like our own.

On the subject of competition: in the pharma market, you compete with the originator, other multinational generic manufacturers, and local generics players. What can you tell us about this ecosystem?

If we look at, say, our generic injectables: our first competition is the originator. As we discussed, in other markets, competition with the originator may not be a major factor, but in Taiwan it is. The first battle we face is the head-to-head clinical trial that I described.

At the next level—the tender process—we will run into price competition. In the tender, if we are competing in a niche that is already very crowded, we could be up against international names like Teva and Sandoz, and formidable local producers such as TTY and CCPC. In that crowded space, price is the main differentiator. The playing field is level: any company has the opportunity to achieve marketing approval. From there, the game is on!

What do you envision for the future of this affiliate?

We will grow in a conservative and cautious manner. We are fortunate that, in the medical device niches where we compete, we have a very dominant position: approximately 90% market share. We are now working to carefully introduce new medtech products, by aligning ourselves with government strategy and focusing on products that we know can be profitable for us. Consumables are a particularly attractive area where I believe new introductions can really contribute to our margins. We are primarily looking into new life cycle initiatives: not changing our hardware in any major way, but rather introducing new consumables, whose revenue is streamlining into our books. We are on a placement model.

On the generic side, we will continue to cautiously assess what molecules we should introduce to this marketplace, be they injectables or biosimilars. If you are first to market in Taiwan with either an off-patent injectable or biosimilar, you will be able to position yourself at a premium price level. On the other hand, entering into a market that has, say, 12 competitors—well, that’s not very fun! Selecting the right molecules, with the right risk profile, is our goal for further generic product introduction.

Over the next three-to-five years, we will look to grow at a modest pace, but above the market rate. We will select the right first-to-market generic molecules to launch, and we will continue to grow our profit margins in the medical device business.

You sound like you have everything mapped out! As a final message to our readers, can you offer some advice to your fellow managers in Taiwan?

The Taiwan market is based on a nationalized healthcare system, with a single payer—the state—covering the majority of cost. As a supplier in this marketplace, you have to manage your reimbursement business very carefully. However, if, at the same time, you can introduce the right products on the self-pay side, you will find that you have a good combination: you will mitigate the risks of aggressive growth in the reimbursement market, where you will face price cuts and heavy competition. If you have the portfolio to play in the self-pay segment in Taiwan, you should. That way, you

can create better balance in your books.

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