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new molecular entities

The Second Generation National Health Insurance Act came into effect in January of this year, introducing a number of major changes to the Taiwanese healthcare framework. Can you please walk us through some of the new regulations that affect pharmaceutical companies in particular?

We can begin by looking at the new Pharmaceutical Benefit and Reimbursement Scheme Joint committee (PBRS). This is a unique committee that is empowered to decide which drugs to reimburse, and how they should be priced. While these decisions were taken by committee prior to the introduction of the Second Generation National Health Insurance Act, the difference now is that the group consists not only of medical-experts, but also representatives from hospital association consumer bodies and employer groups.

To my knowledge, the composition of our committee is quite distinctive compared to other international paradigms. Many countries have non-experts sitting on their pricing and reimbursement committeesâ??but typically, there are very few such persons relative to the total size of the group. Under PBRS , a full 50 percent of the committee is composed of non-experts. We believe that this can create a good atmosphere for true negotiation.

PBRS Joint committee has been in place for several months, and we have had three meetings thus far. It is a work in progress, as the consumer and employer group representatives are not yet very knowledgeable about pharmaceuticals and find it challenging to express their opinions. However, we believe that the committee will improve over time, and we believe that this is the best way to create a mechanism of public participation in the important questions of drug pricing and reimbursement. We also help non-experts to reach conclusions by providing them with the opinions of independent

experts as reference.

We created this balanced committee because we know that sometimes, medical providers may have biased opinionsâ??for instance, if the potential adoption of a new medicine will have a significant impact on their own budgets for healthcare provision. Hospitals, for instance, are given a fixed budget every year, and if they exceed that budget, their payments will be discounted. Medical provider bias is hence understandableâ??but we want to be able to counteract it.

Another new element is the Drug Expenditure Target, or DET. In the past, the BNHI conducted price-volume surveys every two years, and adjusted reimbursement prices accordingly. Under DET, which came into effect in January, the industry instead projects a total expenditure target for the year, and if spending does not exceed the target, there will be no price cuts. We do not yet know what the outcome will be for this first yearâ??but come February 2014, we will be able to understand how well these projections work, and whether spending exceeds the target.

A final provision of the Second Generation National Health Insurance Act worth mentioning is the introduction of Health Technology Assessment, or HTA. HTA will not be undertaken for every new drugâ??only those cases where the expected drug cost exceeds 100 million TWD. We had a loose HTA framework prior to the new Act, but the assessment was not required by law. That has now changed for the most expensive drugs. We do not have the capacity to carry out our own HTA work from scratch, but we are able to reference the reports of regulatory agencies in the UK, Australia, and Canada.

Would you say that this new market environment is sustainable, and attractive for pharmaceutical companies?

As I mentioned, we do not yet know how some of these elementsâ??especially DETâ??will play out. Other elements, like PBRS, will take time to optimize. However, the feedback we have received from the industry indicates that the environment is more stable than it was previously.

Taiwan is trying to attract foreign companies to engage more in the local marketâ??beyond marketing and sales. Will the rewards for these efforts be reflected in pricing and reimbursement incentives?

Indeed, we incentivize companies to conduct clinical trials and pharmaco-economic analyses for innovative drugs in Taiwan. For instance, if a pharmaco-economic study is carried out locally, we offer a ten percent mark-up to the drug producer.

On the subject of incentives, we also recognize that pharmaceutical companies take a global view. Taiwan is a small market, but it is referenced by larger markets like China and South Korea. If we set our prices too low, we realize that companies will hold off on launching their innovative drug hereâ??meaning our patients will suffer. Hence, from last year, we have introduced a number of new policies for new drugs. If the drug is a truly innovative, â??breakthroughâ?? productâ??meaning first-in-class or best-in-classâ??we will price it according to the mean price of a basket of ten countries.

Most of these countries are in Europe and North America; the only Asian country is Japan. The reference statesâ?? GDPs exceed that of Taiwan, so in general, their drug prices tend to be higher. And yet, if our experts believe the innovative medicine in question can provide significant benefit to

the Taiwanese population, we are willing to offer the producer a higher price than we would otherwise. We have thus far classified four drugs as â??breakthrough,â?? under this system.

What else is on your agenda today moving forward?

One of our greatest challenges today is in discerning how to price biosimilars.

A second challenge is developing incentives for our local companies. Our biotech industry is growing very rapidly, and Taiwanese companies are set to release innovative drugs of their own. If a drug is made in Taiwan, then Taiwan must be the first country to reimburse it! This is a difficulty for us, because we will have no international prices to reference. However, what we can do is base pricing on the companyâ??s cost of manufacture. We are currently in discussions regarding how we can optimize that price to reward the companyâ??s innovative efforts. Taiwan will see its first indigenously developed new molecular entity next year. We must be ready. We also must be very clear: we will only accept as innovativeâ??new dosages, new formulations, and etc. will not fall under this category.

Similarly, we must incentivize our local generics manufacturers to improve their standards. Taiwan recently adopted the PIC/S standard. If our manufacturers produce quality drugs in accordance with this standard, we will offer them better pricing.

What is your final message to our readers?

We believe we have created a much-improved healthcare framework. Our aim was to create something that we could sustain for many years to comeâ??ten years, twenty years into the future. Time will tell if we were right!

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