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14.12.2018

Tags: Korea, Association, KRPIA, Market Access

Sean Kim, senior director at the Korea Research-Based Pharma Industry Association (KRPIA) gives his assessment of the role of MNCs within the pharma industry in South Korea.

Could you provide our readers with an introduction to KRPIA?

KRPIA was established about 20 years ago. We have 45 members, all of whom are multi-national corporations. We have a chairman who is from one of the member companies and is elected by the board for a two-year term which can be extended by a further one year at the board's discretion. We also have 16 full-time employees.

Our operations revolve around six special committees working on different areas that affect multinational corporations in the Korean market. These include market access, healthcare policy, research and medical, regulatory affairs, communications and ethical business practice.

How would you assess market access for multinational corporations in the Korean market?

Market access is becoming the most important area for companies. Our members are trying to introduce new drugs as quickly as possible, and therefore, the subject is related to business policy as well as to patient access. At the moment the main concern is that Korean prices are too low.

This was less of a concern in the past when no country was using Korea as a base for their reference prices. This situation has changed. A number of Middle Eastern countries such as Saudi Arabia, in addition to Canada, and in some situations also China are now putting the Korean prices in their reference basket. Given that the size of the Korean market is relatively small, this could have an impact on whether a product is launched in Korea: entering the Korean market with such low prices may affect a company's margins in another larger market such as China.

Nonetheless, the current pricing is very transparent. The list price is the final price. In 2014 the government introduced a risk sharing agreement for limited disease criteria, and thus, for those drugs that qualify, there could be other schemes between the list price and the net price depending on the contract. Currently, this only covers oncology and rare disease drugs. The change was very slow at first, but after 2014 there has been a significant improvement in the reimbursement listing and patient access to oncology drugs has increased. Therefore, this may well be a strategy to expand to other areas in order to address the lower prices for drugs in Korea, in order to maximise patient access and bring drugs to the market as soon as possible.

What are the attitudes of KPRIA's members towards the upcoming Mooncare reforms to the healthcare system?

For pharmaceuticals, Mooncare is building on the previous government's policy for four major disease categories which began in 2013. The previous policy concentrated on expanding coverage for cancer, rare diseases, strokes and cardiac disease, and it became one of the reasons that led to the introduction of the new listing pathways such as risk-sharing agreements and exemption of pharmaco-economic evaluation. They also introduced a compromising fast-track system for drugs, where the company agrees to a particular weighted average price on the basis that negotiations with the NHIS are omitted, increasing the speed of market access at least 60 days.

Mooncare is driving coverage expansion by making non-reimbursable items reimbursable for medical service, medical devices, diagnostics and medicines. Mooncare will require a huge budget if it is delivered as planned. It also impacts the medical and medical devices sectors not only the pharmaceutical sector. Pharmaceuticals comprise 25 percent of total healthcare expenditure, and the biggest proportion is the medical sector. Budget impact will, therefore, be determined by how medical fees including diagnostics are managed well. Many parts of the medical fees are still under negotiation with the government and therefore this time no one can actually estimate the total budget required to deliver these reforms. Nevertheless, we are supporting Mooncare for coverage

expansion with innovative medicines.

Are you noticing the effects of the uncertainty around Mooncare's costs in the market at this time?

There is a degree of uncertainty, as it is believed that the government wants to find any saving alternatives, regardless of the source, meaning pharmaceuticals could be affected. It is known to reinforce the reimbursement policy for entry prices as well as post-listing containments.

Recently the government began to consider reforms to the generic pricing, which were triggered by the safety issue of some anti-hypertensive drug substances affecting over 200 kinds of generic drugs. This provided the government with an opportunity to reconsider the pricing formula, which will put pricing into a downward trajectory.

It appears that the government wants to bring back the old pricing formula. At the moment there is the same price for the same molecules, whether patented or off patented. When a generic is listed the price of the original is readjusted down to almost half within a year and generics are given the same price ceiling.

While generic penetration in Korea is around 60-70 percent, it is interesting to see the volume increase for some off-patent originals, despite the fact that there can be up to 80 generic alternatives in some cases. This is the result of poor policy by the government. While lowering the price of the off-patented original is good in the sense that lowers cost to the system, the policy ignores the fact that brand loyalty exists everywhere and in the rest of the world, generics are a cheaper alternative. When generics and biosimilars are set at the same or similar price as the originals, there is no reason for physicians, pharmacists and even patients to choose the generic over the original product.

A voluntary generic discount could occur in the market for competition but too low prices in the home country can affect invoice prices to other markets when globalized.

Lowering prices could also impact on both the virtuous cycle of domestic R&D and entry prices of new drugs referencing weighted average price for listing.

What do you see as the role of MNCs in bringing innovation to the country?

Domestic companies are still too small to invest in the whole R&D value chain from discovery until phase III clinical trials. MNCs are also changing their research patterns, looking more and more for good partners at the various stages of R&D across the globe. Consequently, partnerships for open innovation are the optimal strategy for everyone. Korean companies have good resources, techniques and know-how, but do not have experience in penetrating global markets alone. We are encouraging our member companies to form partnerships with local companies ranging from basic research and R&D to even global marketing partnerships.

How willing are MNCs to go and establish partnerships with Korean firms?

There is some resistance. One of the questions we need to ask is how we can bring the investment of international pharma companies to the Korean market. Korea is only 1.5 percent of the total global market. Although Korea has a good infrastructure particularly with hospital clusters, we are not the only country seeking valuable partnerships who possesses. The landscape is highly competitive.

For KRPIA, we have organised an annual event called KPAC-the Korean Pharmaceutical Associations Conference. The aim of this conference is to foster open innovation. This allows our global members to connect with local pharma ventures and research hospitals who may have interesting research assets or pipelines. Our aim is to build a platform where we can promote the Korean market. They can meet with Korean leaders and policymakers to discuss partnerships. A separate partnership program for Start-ups in Korea has been established this year in collaboration with KOTRA, in which the experts of our member companies will assist them in globalizing.

A good example is the agreements between Hanmi, Sanofi and Lilly for a partnership and co-development agreement. Moreover, Yuhan recently signed an agreement with Jansen to develop an oncology product. This is a positive sign for the future; if this happens more often, Korean policymakers will be forced to understand the value of MNCs as partners for the Korean healthcare market.

What would be your message to the government in terms of policies that need addressing to make career stand out on the global stage?

Firstly, the size of the Korean pharmaceutical companies remains small. In order to increase the scale of economy, it will require more investment from other sectors such as the financial sector or

even other industries. The government’s policy toward rewarding innovation could make this happen.

Secondly, the government needs not only to concentrate on foreign investment in Korea, but also consider the value of the MNCs operating within Korea. Multinational companies have a long history of drug development. Therefore, we require their advice and know-how if we are to develop this innovation and expertise for ourselves. This can be a short-cut to truly globalising our pharmaceutical industry.

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