Tan Sri Rahman Mamat – Chairman, Inno Bio Ventures, Malaysia

There is a strong potential for exporting biosimilars [from Malaysia], conditional on us transferring the technology

21.11.2018

Tags: Malaysia, Biosimilars, Manufacturing, Inno Bio Ventures, SOE

Tan Sri Rahman Mamat, chairman of Inno Bio Ventures, provides his vision for biosimilars' potential in Malaysia, and the progress the company has made in laying the foundations to make Malaysia an export hub for biological products in the future.

Could you introduce our readers to the Malaysian government's vision regarding biosimilars and how Inno Bio Ventures facilitates this?

When the government first created Inno Bio Ventures, its main focus was to create drug security by ensuring that the country was self-sufficient in the supply of medicines. Otherwise, Malaysia is at the mercy of Forex (foreign exchange) markets and shortages if the exporter encounters production issues. Moreover, statistics show that the growth in pharmaceutical consumption is in the double-digits. The Ministry of Finance is often castigated for allotting insufficient funds for medicines, but simply increasing the budget is unsustainable. Therefore, the government is focused on prevention and producing cheaper drugs locally, in the form of generics and biosimilars. As a trading nation, we added the element of export potential of local products.

Originally, Malaysia looked at entering the medical devices market, with a view towards becoming the regional hub for production. However, the venture was deemed unfeasible following the emergence of competitors such as China and Vietnam, which could produce at a lower cost.

Subsequently, Inno Bio Ventures became involved in the contract manufacturing of biosimilars, another area of interest for Malaysia. We had experience working with India, Korea, and Japan. Nevertheless, we encountered the same problem of pricing. Thus, we altered our strategy of working autonomously and moved to joint ventures.

How successful have you been in finding joint ventures?

It is difficult to find the right partner to establish a joint venture for two main reasons. Firstly, the Malaysian market is not big enough to find adequate partners. Secondly, international suppliers are more comfortable with simply importing and supplying their drugs locally through distributors or representative offices as they are reluctant to hand over their technologies to a third party.

We eventually found an Iranian partner Ayrogen, with whom we formed a joint venture and we received an award for this joint venture from the D-8 organisation, a group of Islamic countries that are heavily populated consisting of Malaysia, Indonesia, Turkey, Iran, Nigeria, Egypt, Pakistan, and Bangladesh. It was labelled as the best joint venture effort to develop biosimilars as a solution for D-8 countries. Hence, our project will bring benefit not just to Malaysia, but to patients across the Islamic world. However, we encountered a setback when sanctions were re-imposed on Iran. As a result, their products were only recognised in Iran, and not by the FDA or the EMEA. As it was unacceptable for the Malaysian authorities, it led us to delay our project in this country.

How do you find the right partners for joint ventures and demonstrate that both Inno Bio Ventures and Malaysia are open for business in the biosimilar sphere?

We benefit from a strong international network. As a government-owned company, we have the support of the Ministry of Finance and MIDA, along with contacts with our ambassadors worldwide. For example, a company from South Korea came and visited MIDA, who in turn referred them to us. We were able to immediately showcase our facilities, and less than a month later we signed a collaboration agreement with them.

As we are incorporated under the Ministry of Finance, we are collaborating with Khazanah, the sovereign wealth fund. They have invested in life sciences and own the largest share in the IHH Healthcare corporation, not only one of the largest private healthcare providers in Malaysia, but also the owners of Acıbadem Healthcare Group, the largest healthcare provider in Turkey. Subsequently, we are liaising with them to create synergies and promote our products through

their healthcare apparatus, which they are expanding beyond Malaysia and Turkey into Eastern Europe. In this regard, marketing is not a major concern for us as we benefit from their network.

How would you evaluate Malaysia's potential to become an export hub for biosimilars?

There is a strong potential for exporting biosimilars, conditional on us transferring the technology. Given the political conflicts between Iran and the Arab world, Ayrogen's intention is to use Malaysia as a hub as we are seen as the intermediate for its products to be accepted in the Arab states of the Middle East. We are fortunate as the Middle Eastern countries are connected to Asia through Islam. Consequently, they look to us as a gateway to ASEAN markets. For example, Ayrogen has permitted us to export products to China. In contrast, ASEAN countries are linked geographically to Malaysia, and want to utilise our connections to the Muslim world to penetrate the Middle East. In this regard, we are currently in negotiations with a South Korean company wishing to use Malaysia as a hub to penetrate the Middle Eastern market.

Moreover, excluding biosimilars, there is an opportunity to develop the plasma segment in Malaysia, again based on the security for the country's supplies. Negotiations with the government and the state blood bank are ongoing. Many other D-8 countries need this service, so we can launch export opportunities here too at half the price of the current suppliers.

What is the timeline for the launch of Inno Bio Ventures' first product?

We require another 18 months to two years before our first product, Factor VII, developed in collaboration with Avrogen, reaches the market and we will be able to call ourselves a producer, and an exporter. We have submitted the registration. However, Ayrogen conducted the original clinical trials in Iran, which unfortunately failed to satisfy Malaysian quality standards. Consequently, we must rerun them locally to verify the safety and efficacy of the product.

In addition to our joint venture with Ayrogen, we received the approval to produce the biosimilar Epoetin, following the technology transfer from a German firm. This is now ready for marketing. However, it is not sufficient to only have a stable supply of drugs. They must also be accessible to the patients and effectively treat the disease. Hence, we concentrate on developing and producing drugs that are of most value to the needs of Malaysians. Therefore, we have identified four therapeutic areas to produce products for breast cancer, arthritis, leukaemia, and blood disorder, all in great demand in both Malaysia and our targeted export markets.

How have your manufacturing capabilities been evolving since the establishment of the company?

Our facilities are composed of state-of-the-art German technology which was a RM 150 million (USD 36 million) investment. We are in the process of obtaining FDA and EMEA approval which is required to manufacture a product in Malaysia. The accreditation is expected within the next 12 to 18 months. In addition, having EMEA and FDA approval eases the challenge of penetrating foreign markets. We are considering declaring the region where our factory is located as a pharmaceutical hub.

We also have an agreement with a Turkish company, Nobel Ilac, to produce some of their generic products in our factory. This company is also involved in biosimilar production. As their facilities will not be ready until 2023, they intend to use our facilities to advance their projects and we have 25 acres of land adjacent to our facilities that we can expand into.

What are the main challenges that you have encountered since embarking on this biosimilar journey?

Our main challenge is creating a product at a competitive price. If we enter public sector tenders, multinationals who loom to capture the market will undercut us. The government allows us to offer prices up to ten percent above the lowest bid but in most cases, the tender will be one by the lowest bidder. Hence, we are in negotiations to decrease the price so that we can compete with multinational companies. Given that we rely on economies of scale, our strategy is primarily to establish a market share.

One of the subsequent challenges is to maintain the government’s enthusiasm for biosimilars. Given that there are cheaper alternatives, we must rebuff any short-sighted thinking. There have been complaints, both from the industry and from policymakers that we have advanced too slowly. Some have used this as a justification for leaving biosimilar development to the private sector as this is a very high-risk venture.

What final message would you like to send to our international readers?

I want Inno Bio Ventures to be known as a biosimilar producer, open for joint ventures and with the capability to expand. The objective moving forward is for Inno Bio Ventures not just to become profitable, but to ensure that we can assist patients with the costs of healthcare and increase access to medicines in Malaysia. We do not look to promote Inno Bio Ventures, but healthcare services.

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