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We need a strong independent regulator with a one-country, two-way system framework that takes China into consideration

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Commonly regarded   the father of Hong Kong biotechnology  , Professor Lo Yuk Lam has had a hand in almost all of the city  s biotech success stories, including those of Michael Yang and Dennis Lo. Professor Lo has been heavily involved in several Hong Kong governmental committees, is an Honorary Professor of a number of universities in China, and is the Founding President of HK Bio-Med Innotech Association. In conversation with PharmaBoardroom, Professor Lo outlines Hong Kong  s journey towards translational science and commercialized biotech innovation, and why a fully-fledged Hong Kong medicines regulator is crucial for the city to take the next step in its development.

Hong Kong is extraordinarily strong academically, but its researchers have historically not often been able to translate their science into commercial success. How would you explain this?

Hong Kong began its technological development with a blank sheet of paper and the government put forward no plan of attack, let alone a concrete plan for biotechnology. There was little talk about investing in innovative areas and we were more focused on sectors such as textiles and continuing to position Hong Kong as a trading hub. There were seven committees, and biotech was one of

them, but no legislation supported a targeted framework, despite my work to found a biotech bureau at the time.

What is your experience within the Hong Kong biotechnology ecosystem?

I have always worked in Hong Kong and have been part of the push for biotechnology for decades, even setting up curriculums at the university level centred around this sector. The reason I have had such a strong interaction in the field is I was managing the Hong Kong government funding for applied research starting in 1986. I then did this through the transition from British to Chinese rule, which is why so many of the leading scientists we have here today know me well. Back then nobody knew anything about biotechnology in Hong Kong, it was a complete unknown, but still, we chose to support researchers in this field

Hong Kong has shifted from a pure trading hub to becoming more industrialised. How did this first come about?

Tung Chee-hwa [the first Chief Executive of Hong Kong between 1997 and 2005, upon the transfer of sovereignty from the UK on 1 July 1997] had a vision for Hong Kong innovation back in the 1990s and he set up a technology policy that led to the development of the Hong Kong Science Park and Cyberport. The problem was that he was a mainland China appointee and many of the people in the sector were coming from British rule, so did not listen to his vision and wanted to do their own thing

Do you have the feeling that we will see a shift here and possibly a rise in local biotechnology companies?

The part of the world we lived in is a planned economy, even Hong Kong. To date, a commitment of over HK\$100 billion has been made in innovation and technology, with 60 percent in life sciences and 40 percent in AI and robotics. For Hong Kong to take the next step forward the government needs to have a better understanding and gain knowledge on how to spend that money.

If you want to promote Hong Kong as an innovation hub you must invest in R&D. Investment globally as a percentage of GDP follows similar guidelines to that in Western countries, around 3 percent, with China at around 7 percent. Hong Kong is on the other side of the spectrum at less than 1 percent. Even though we are investing more than ever before, it is a fraction of our competitors in the global marketplace.

Nevertheless, you must look beyond the numbers and understand what they exactly mean. In these other countries, like the US, Japan and European nations, around 70 to 80 percent of R&D spending is coming from the private sector, an area where Hong Kong has next to nothing in place, leading to this lack of funding.

How are you looking to change mindsets and in turn help grow Hong Kong's biotechnology ecosystem?

If you look at other countries, they are assisting companies in their R&D operations. If companies invest in research in a country, they receive incentives from that country's government, such as tax breaks, reimbursement, and wage contributions.

Furthermore, Hong Kong does not have its own fully fledged regulatory agency for the sector and there seems to be a lack of willingness to understand the legal and compliance parts of biotechnology. If you look at similar smaller markets like Singapore, they have a system in which new drug discovery R&D being performed there has a pathway to achieving independent regulatory approval. Biotechnology companies will not conduct R&D here if it is not internationally recognised, so we must reach the relevant international levels so we can compete with other markets in attracting investment within biotechnology start-ups and global R&D for large companies.

But this regulatory framework can be built, so why has it not been?

We need a Hong Kong version of the FDA, and not one that is just for the Chinese system, this is the logical approach. We have the chance to be a bridge between the West and China for regulatory approval and this will position us better. The authorities want a regulatory body equivalent to the US, Japan, and Europe, so why not include approval for China also and act as the gateway jurisdiction?

We are meeting the international standard in clinical trials, so why can we not do it for investigational new drug applications (INDs) in biotechnology? If you want to put in place the next steps of the chain like manufacturing, you first must build a strong foundation. A lot of pushback is people saying we have used the old system for 100 years, so why change? You change because it will work better, not because things have worked in a less efficient way in the past. We need a strong independent regulator with a one-country, two-way system framework that takes China into consideration.

Clinical trials are a good first step in R&D. Do you see possibilities there for Hong Kong to first establish itself as a larger player in this field and then move into more advanced areas of discovery?

We have no clinical trial-specific hospitals and only three certified hospitals. Also, and this is nobody's fault, Hong Kong is small and does not have a large enough population for many clinical studies. Another point is that we have an excellent public healthcare system with great doctors, but they are primarily driven to help the patients in front of them and have no interest in research. They could change their mindset, and maybe being part of more clinical studies will help, but this takes a lot of time and a shift in mentality.

I will also say that in Asia we are hung up on developing large and small molecules but are behind on cutting-edge discoveries in more complex areas like gene therapy, cell therapy and infectious diseases. The Western world, especially the US, is dominating this area. Despite all this, we cannot talk too much about Hong Kong being a larger global R&D player until we make sure regulation is internationally recognised. Without this, the conversation is redundant.

The Hong Kong Stock Exchange's Chapter 18A, allowing for pre-revenue biotechs to list, was set up in 2018 with a view towards fostering biotechnology growth. What is your view on it?

It was created as an ecosystem for Chinese scientists to raise money for their companies. I think it was a good idea and it is the second largest of its kind in the world and the largest in Asia. Nevertheless, if you compare it to the competition, the NASDAQ, it is not as appealing. This is not helped by the fact we lack great business analysts in Hong Kong, and we are not able to properly value what a company is worth, which makes it a bit more complicated.

And moving forward what would be your message?

We need to set up this Hong Kong regulatory body as soon as possible and get the medical community involved in research. With this, we will see a rise in activity within the Hong Kong biotechnology ecosystem.

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