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With the amount of data available through Hong Kong's Hospital Authority database, precision and personalised medicine could be a good focus for the city

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The Hong Kong Association of the Pharmaceutical Industry (HKAPI) represents the interests of the global R&D-based biopharmaceutical industry in Hong Kong and Macau. Senior Executive Director Sabrina Chan outlines the access to innovation scenario in the territory today, the niches in which Hong Kong stands out from the crowd as a biopharma investment destination, and her hopes for increased collaboration across the city's healthcare ecosystem moving forward.

Just for starters, what process is in place for the registration and approval of new pharmaceutical products in Hong Kong today?

Hong Kong’s regulatory system is a secondary review system for new chemical entities (NCEs) and until last November we required CPP (Certificate for Pharmaceutical Products) approval from all of the 32 International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) nations on our list.

Since then, we have added four nations: South Korea, Brazil, mainland China, and Singapore. Moreover, since February 2023, CPP approval from only two of the 36 reference countries in the list is required for drug registration. In exceptional circumstances – such as when a product meets an unmet local need around a public health emergency in communicable or infectious diseases – only one CPP approval is needed, along with an assessment report from a local expert. CPPs from the

European Medicines Agency (EMA) represent multi-country approval in Hong Kong.

How well do you feel that the Hong Kong government rewards biopharmaceutical innovation entering the market?

It is important for the government to offer more incentives to attract clinical trials and the application of real-world data in Hong Kong. This could include expedited access to public sector institutions for medicines that have undergone local clinical trials, and the use of real-world data generated across the Greater Bay Area (GBA), including Hong Kong, in drug registration and reimbursement in the People's Republic of China, including Hong Kong.

Many Chinese companies are using other destinations, including Australia, as a hub for conducting more internationally recognised R&D. What advantages does Hong Kong have over this competition?

Hong Kong has world-class hospitals and universities, five of them being in the global top 100 with lots of international investigators

The GBA gives us the advantage of a sizable patient pool, something Hong Kong does not boast on its own.

Finally, the Hong Kong Hospital Authority (HA) has maintained and stored the health records of 90 percent of inpatients for the last 31 years, which is a very good source of patient data. Hong Kong must now develop a method of leveraging this data to undertake clinical studies.

Pricing negotiations with payers in any given market are crucial for the commercial viability of companies present. Who is the payer within the HKSAR?

The public payers, including the Department of Health for public health, and the HA as the key public services provider, use tendering systems for the procurement of medicine

A new Primary Healthcare Blueprint has been put in place and a Strategic Purchasing Office is being developed to purchase products and services in primary healthcare.

The private sector has its own procurement process for its hospitals, clinics, and pharmacies.

What are the items currently at the top of HKAPI's agenda?

HKAPI's mission is always to drive the expedited access of innovative healthcare solutions to people in Hong Kong. The key initiatives for HKAPI today are around primary healthcare, with the activation of the new blueprint and patient journey navigation which ensures the accessibility, affordability, and availability of medicines. Other areas we are focused on include big data and planning for medical advancement and clinical trials, and synergising the government's GBA initiatives. This includes supporting the rollout of Hong Kong-registered drugs to the entire GBA, leveraging the region to enhance Hong Kong's clinical trial capacity, and applying real-world evidence and clinical trial data for drug registration and reimbursement in both mainland China and Hong Kong.

What are some examples of work that HKAPI has undertaken as an association to help establish Hong Kong as a clinical development/trials hub?

Other than providing our views on policy and regulatory framework enhancement, we developed some pilot projects to proof of concept stage. We collaborate with the University of Hong Kong on Horizon Scanning studies to look at unmet needs and compare them with the upcoming pipeline in depression, IBD and prostate cancer. This has allowed us to develop a more forward-looking planning on drug registration and budgeting.

Hong Kong is very attractive for pharmaceutical companies and we believe that with the amount of data available through our HA database, precision and personalised medicine could be a good focus for the city. We would be able to leverage these fields in two ways. Firstly, precision/personalised medicines would give us a better understanding of the patient journey during treatment and secondly it would enhance the positioning of Hong Kong as a biomedical hub.

Do you believe that the relatively diminutive size of Hong Kong deters companies from establishing or expanding their operations here?

We did not wake up this morning to suddenly find that Hong Kong was small! This has always been the case and we know we can never compete on market size alone with other markets. What we do know is that Hong Kong is a strategically important market that is a gateway between China and

the rest of the world and vice versa.

What are your goals moving forward and what role do you want HKAPI to play in the development of Hong Kong?

Nowadays the connection between the pharmaceutical industry and government is good but can be improved. Today, our members represent the entire healthcare ecosystem across the product life cycle including pre-clinical and clinical trial centres, R&D-based pharmaceutical companies, distributors, and patient groups. Additionally, with the patient journey in mind, HKAPI members also include diagnostics companies, software companies providing analytics of genetic variations via patient apps, and law firms with a specialisation in intellectual property (IP) protection.

We want to be part of healthcare solutions for Hong Kong. We are open to working with other associations and institutions to better understand what steps we can all take to improve the health of patients. We know that working alone will not bring success and all challenges must be solved by multi-stakeholder action. Collaboration is the key to reaching our goals, and we are ready to partner with people who understand that.

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