

# Sabrina Chan - Senior Executive Director, Hong Kong Association of the Pharmaceutical Industry (HKAPI)

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*Sabrina Chan, senior executive director of the Hong Kong Association of the Pharmaceutical Industry (HKAPI), an organization that represents the innovative pharmaceutical industry in Hong Kong and Macau, weighs in on regulatory improvements in the territory such as the OnePlus mechanism and the Centre for Medical Products Regulation; discusses HKAPI's aim to develop a Greater Bay Area R&D network and thus expand the reach of clinical trials; and reviews the recent developments in data sharing with the Hong Kong Hospital Authority.*

## **Over the past year, what have been the most important regulatory updates in the Hong Kong pharmaceutical market?**

The two most notable changes have been the implementation of the "1+" (OnePlus) regulatory mechanism and the development of the Hong Kong Centre for Medical Products Regulation (CMPR).

The "OnePlus" mechanism allows for the approval of new drugs in Hong Kong if they have been approved in only one reference country, provided they are supported by local clinical data and there is a local unmet medical need. Previously, all drugs needed to be approved by at least two separate regulatory authorities from 36 reference countries such as the US FDA, authorities of countries in Europe and Asia and gain a Certificate of Pharmaceutical Product (CPP) from two of them (EMA is multi-countries) as pre-requisite for registration in Hong Kong, with an exception of

diseases related to public health. This regulatory upgrade aims to expedite the approval of innovative drugs for severe illnesses and unmet medical needs, enabling faster patient access. The “+” component refers to the requirement of local clinical data and recognition by relevant experts in Hong Kong.

Another key initiative is the establishment of the CMPR, which is a proposed regulatory authority to enhance the regulatory framework for pharmaceuticals, medical devices and Chinese medicine under the same umbrella as the foundation to develop Hong Kong as a biomedical hub in structure. The Preparatory Office for CMPR will study the potential restructuring and strengthening of the current regulatory and approval regimes, with the long-term goal of creating an internationally recognized regulatory authority that can conduct primary evaluations of drugs and medical devices, in addition to the reliance only on secondary reviews.

These regulatory reforms are part of Hong Kong’s strategic plan to improve patient access to innovative medical products and strengthen its position as a hub for pharmaceutical and medical device development in the region.

**How have HKAPI’s members responded to these changes, and have they influenced their approach to introducing new medicines?**

Our members’ response to the initiative primarily centred on the need to retain the secondary review route. Reliance pathway is a system allowing health authorities to leverage expertise from each other and make innovative medicine available to patients faster. Flexibility in the regulatory framework is paramount, akin to the multi-route approach seen in other markets like Singapore. Efficiency, professionalism, international recognition, and predictability are the cornerstones of an effective regulatory system. It is crucial that any changes do not inadvertently prolong the review process, as competitiveness with other markets is key. Ultimately, the question arises: Why should companies choose to register their products in Hong Kong earlier? This underscores the importance of ensuring that the value of our regulatory processes is internationally recognized, providing a compelling reason for companies to opt for registration here earlier, which will ultimately benefit patients in Hong Kong.

**How significant would the establishment of an independent regulatory body of its own be for Hong Kong? Are you advocating for this?**

While becoming an independent regulatory body could support biomedical development, what is crucial is maintaining a system that offers flexibility while adhering to the four essential criteria: efficiency, professionalism, international recognition, and predictability. It is vital to focus on the why before delving into the how. We must consider the value such a change would bring and ensure alignment with international standards, particularly given the multinational nature of our association's representation.

**If the regulatory landscape were to transition towards a primary review system, would this increase operational costs for companies?**

It is not just about cost. What is critical here is to ensure Hong Kong's regulatory framework remains aligned with international standards and being recognized by many markets. We have been discussing regional reliance and the importance of Hong Kong's integration into the global arena. International recognition is paramount, especially considering Hong Kong's aspirations to become a super connector. However, amidst these ambitions, we must not lose sight of the primary objectives of any regulatory system: ensuring the efficacy, safety, and quality of medicines, as well as facilitating access for patients, in addition to enhancing Hong Kong's R&D. This underscores the need for efficiency, professionalism, international alignment, and predictability within the regulatory framework, all the while maintaining flexibility.

Across Asia, there is a strong focus on regulatory reliance, where countries leverage each other's resources to expedite the drug registration process and enhance mutual learning and recognition. For instance, within alliances, different countries' assessment groups work collaboratively in evaluating a drug dossier while remaining independent in the final decision making.

For Hong Kong, developing primary review capabilities could start with joining such alliances, learning from others, and gaining international recognition. Starting with a collaborative approach can help build a robust system, ensuring that Hong Kong's regulatory framework is both efficient and globally respected.

**A Greater Bay Area (GBA) International Clinical Trials Institute has recently been established. What are your thoughts on these collaborative efforts and their potential impact on the regulatory landscape?**

We aim to develop a GBA R&D network, and we are now focusing on the implementation steps. One of the key advantages of this initiative is the ability to conduct larger-scale trials, particularly in areas like nasopharyngeal carcinoma, hepatitis B, and infectious diseases, where the GBA offers a significantly larger pool of patients. Additionally, the presence of renowned principal investigators and hospitals adds to the credibility and expertise of the trials conducted in this region.

However, while the potential benefits are evident, it is equally important to address the challenges associated with establishing an efficient and professional setup for clinical trials. Efficiency remains a paramount concern, especially in expediting the setup of trials to ensure competitiveness with other regions. Furthermore, ensuring professionalism across the entire GBA is essential to maintain high standards and credibility.

Moreover, the value of clinical trials extends beyond just contributing to multinational trials. It is essential to consider how these trials can directly benefit Hong Kong, such as by contributing to regulatory approvals, like those from the mainland Chinese NMPA, or facilitating access to markets. By aligning with strategies similar to those employed in Taiwan, where local trials offer advantages in market access, we can maximize the impact of clinical trials conducted within the GBA. Ensuring adequate incentives for investigators is essential not only to encourage their participation but also to attract multinational pharma companies to conduct trials in Hong Kong and the GBA. To achieve this, we need to craft a compelling narrative that highlights the advantages of our region. This includes emphasizing the presence of internationally renowned principal investigators, an efficient trial setup, and access to a diverse patient pool.

Moreover, we must equip Hong Kong general managers with the tools and arguments necessary to persuade global leaders and management teams to invest in clinical trials in our region. By showcasing our strengths in professionalism, efficiency, and availability, we can instil confidence in potential investors and stakeholders. At the same time, Hong Kong general managers are key stakeholders that the government can solicit their input to improve the system and make it more conducive to investors.

### **Has there been any progress in making Hospital Authority (HA) data more available for clinical trials or real-world evidence?**

There have been some steps forward, such as setting up HA Data Collaboration Laboratory (HADCL) for secured data sharing. In addition to collaborations with local academic institutions, Hong Kong Science and Technology Parks Corporation (HKSTP) and HA have launched HKSTP HA

DCL with direct access to around 200,000 patient anonymous clinical data from HA's database for non-academic research and development purposes. However, questions remain about whether this is sufficient and the flexibility of the current system. There is a call for a more expedited and inclusive approach to accessing this valuable data, drawing inspiration from other countries' models.

**Having recently spoken at a panel discussion about Hong Kong start-ups, what progress have you seen in terms of biotech and healthcare ventures?**

There is definitely momentum building. Over the years, we have seen a rise in spin-off start-ups and a more mature approach to pitching projects. This year, particularly, there has been a noticeable improvement in the quality and maturity of projects presented. While some investors may have turned more conservative due to market conditions, it is ultimately beneficial as it filters out weaker projects and emphasizes the importance of solid ideas and planning. This evolution process is fostering a healthier ecosystem where only the strongest projects survive. Overall, there's a positive momentum with clearer and more mature discussions among investors, inventors, and entrepreneurs alike.

**What market dynamics have your members witnessed in 2023 and 2024?**

The landscape has been evolving, particularly with a focus on primary healthcare. We have seen the emergence of strategic procurement offices and initiatives like the Chronic Disease Co-Care (CDCC) Pilot Scheme signal a shift in healthcare procurement dynamics. Traditionally, there has been a reliance on existing structures like the HA and Department of Health for procurement, given their established systems. However, innovative healthcare systems recognize the necessity of catering to a separate consumer base, distinct from the HA. This consumer base is composed of individuals identified by the CDCC Pilot Scheme as at risk for chronic diseases such as diabetes and hypertension. These individuals may seek care from general practitioners rather than HA doctors and co-payment could be involved. Thus, there is a need for a different approach to procurement, one that tailors medications and services to meet the specific needs and expectations of this consumer group. By implementing separate drug supply models and adopting innovative strategies, we can better address the challenges of a shifted healthcare focus, ultimately shaping the market dynamics in the future.

Expanding on the implications of healthcare dynamics in the GBA, it is evident that the interplay between Hong Kong and mainland China is becoming increasingly significant. With the flexibility of Hong Kong residents moving between regions, including for retirement and work purposes, and the landscape of medical tourism is evolving. Previously, the flow was predominantly from China to Hong Kong, but now there is a notable trend of Hong Kong residents staying within the GBA.

Moreover, the recent initiative allowing Hong Kong registered drugs with urgent clinical use to enter China for use in designated hospitals in the Greater Bay Area, underscores the importance of streamlined registration processes. While this initiative has seen some progress, there's still room for improvement, particularly in expanding the coverage of designated hospitals and categories of drugs.

Additionally, the integration of real-world data from Hong Kong into registration processes and reimbursement decision in the mainland holds great potential for enhancing healthcare policies and practices. Leveraging the rich pool of real-world data available in Hong Kong, alongside that in the GBA, could significantly bolster the registration process, making it more robust and reflective of diverse patient populations and treatment outcomes.

Overall, the healthcare dynamics in Hong Kong and other GBA cities presents opportunities for improved collaboration and innovation, with the potential to drive meaningful advancements in healthcare access and quality across the region.

**Are there any ongoing collaborations or projects that the association has on its agenda for 2024 and 2025?**

We have several important initiatives on our agenda. Firstly, we aim to foster more collaborations with the Guangdong part of the GBA (GBA). Specifically, we are focused on expediting the access of Hong Kong-registered drugs in China and increasing the number of designated hospitals and making real world data a reference to drug registration in China. Additionally, we are committed to enhancing R&D capabilities both within Hong Kong and through collaborations with the GBA.

Secondly, it is vital to have a champion for the development of a biomedical hub by strategically coordinating the implementation plan of different bureaus, departments, statutory bodies (HKSTP, HA) and industry, with as a platform to achieve common goal. It can be similar to the Office for Life Sciences in the UK would facilitate regular discussions and streamline information sharing, ultimately benefiting people and patients in Hong Kong and Macau.

Lastly, we are keen on strengthening communication channels between Hong Kong and the GBA to leverage policy changes and promote collaboration in areas like drug registration in China. By ensuring effective communication and collaboration, we can better advocate for policies that expedite access to innovative healthcare solutions for the benefit of patients in Hong Kong, Macau, and GBA

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