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Sabrina Chan, Senior Executive at HKAPI, highlights progress in Hong Kong's biomedical ambitions, including establishing an independent regulator, expanding clinical trial capacity via the Greater Bay Area Clinical Trial Institute (GBAICTI), and leveraging 34 years of real-world health data. She underscores efforts to enhance primary healthcare, support rare disease access, maintain R&D for innovative medicines, and develop sustainable pathways for clinical trials and reimbursement in 2026.

Looking back over the past 18 months since we last spoke, what progress has been made on drug access in the Greater Bay Area, R&D capabilities, and Hong Kong's biomedical hub ambitions?

Two developments are particularly important. First, there is now a clear timeline for establishing the Centre for Medical Products Regulation – an independent regulator for Hong Kong. When we last discussed this, it remained a complex plan for implementation. Now it is approaching reality. The CMPR is planned to conduct its first primary review within this year. This represents rapid movement from concept to implementation.

This matters because Hong Kong sees itself as a superconnector with ambitions to become a biomedical hub. It is essential to attract overseas investment to Hong Kong and establish robust supply chains. As a biomedical hub, we must ensure effective transformation from bench to

bedside. If we examine the product lifecycle – from molecule through preclinical development, clinical trials, product registration, to market – primary review will support local pharmaceutical innovation, local research and development, and particularly help attract more strategic clinical trials to Hong Kong for registration purposes.

Because we will have primary review capability, some Chinese companies seeking overseas markets may leverage Hong Kong's independent evaluation, whilst overseas products could use this pathway to access China. This creates synergy supporting Hong Kong's dual ambitions.

What is the expected timeline for establishing Hong Kong's new independent regulator?

The plan aims for full transformation by 2030. This is an enhancement, not a creation, building on Hong Kong's existing secondary review framework. We can conduct primary evaluations while simultaneously developing a reliance network with established global authorities. This approach accelerates the process and strengthens the regulator's capacity – both in quality and scale – which remains the key priority.

In the shorter term, what impact is this move towards primary review having on access to innovation within Hong Kong today?

The impact largely depends on capacity and system efficiency. Primary evaluation does not automatically speed up timelines if capacity is limited, but with proper capacity building, it can be achieved. The key advancement is the introduction of multiple registration pathways.

Companies and R&D organisations now have greater strategic flexibility compared with the past, when only secondary review was available. This optionality represents one of the most significant improvements. For instance, the '1+' mechanism we currently have in place, allowing for a single certificate of pharmaceutical product 'plus' local data (such as clinical trial data, real -world evidence, and expert recommendations, often related to how a drug works in Asian populations) has fostered access to innovation within Hong Kong.

For the time being, we will continue to maintain multiple pathways – primary evaluation, secondary review, and the 1+ mechanism. What matters most is that companies can now choose different regulatory strategies.

A second major development is the establishment of the Greater Bay Area International Clinical Trial Institute. As previously discussed, Hong Kong has strong clinical trial capabilities, with highly trained principal investigators and excellent data integrity.

That said, Hong Kong is a small city with a limited population, which constrains recruitment. The GBAICTI aims to combine Hong Kong's clinical expertise with the significantly larger patient pool of the Greater Bay Area, which has a population of around 90 million.

By bringing these strengths together, the GBAICTI can support larger-scale recruitment, more efficient patient referral, and closer ecosystem collaboration. When discussing research and development, it is important to consider the ecosystem as a whole. Hong Kong alone may be small to operate in isolation, but by expanding into a broader geography, we can leverage complementary capabilities and create meaningful synergy.

The third important development is real-world data. Hong Kong has a unique asset in the Hospital Authority patient record system, which now contains 34 years of longitudinal data. The system is unified under a single administrative framework, maintained in English, and supported by strong verification cohorts.

Depending on how it is utilised, this data can support drug discovery, post-market surveillance, service enhancement, and enlistment decisions . Given Hong Kong's strong track record in innovative medicines, this represents a particularly valuable resource.

How does Hong Kong balance access to real-world data with data privacy, and how could Greater Bay Area data support regulatory and reimbursement decisions?

It largely depends on how much data can be made accessible to private actors. When dealing with sensitive public health data, there is always a balance between enabling research and maintaining appropriate safeguards. This is precisely the challenge we need to address.

There are many global examples demonstrating how data can be tiered according to sensitivity, allowing access while preserving privacy. The solutions exist, and the challenge should not outweigh them.

This is particularly relevant in the Greater Bay Area. Special measures already allow Hong Kong-registered drugs and medical devices to be used in Greater Bay hospitals. Policy also supports the use of Greater Bay Area data, especially for products not yet registered in China, where such data

could contribute to regulatory submissions or reimbursement considerations. Taken together, data from Hong Kong, Macau, and the wider Greater Bay Area could play a meaningful role in supporting both regulatory and reimbursement pathways.

How will the Hong Kong government's current prioritisation of primary healthcare policies affect your members, and how are they supporting these goals?

Over the past two years, we have worked very closely with the Strategic Procurement Office on primary healthcare initiatives, and we strongly support the government's direction to strengthen primary healthcare services in Hong Kong.

We have engaged in discussions on the Chronic Disease Co-Care Pilot Programme and the Community Health Centre model. While these initiatives remain under review, we see them as positive steps towards enhancing community-based care.

With an ageing population and growing pressure on hospital services, the current system is clearly not sustainable in the long term. In this context, the role of community pharmacists and pharmacies has become more important. Establishing community pharmacists across different districts expands their role in patient care, improves access to pharmaceutical advice, supports medication adherence programmes, and provides more convenient consultation for patients, including those who travel to obtain medicines. Overall, these measures help make primary healthcare more accessible and patient-centred.

With Hong Kong's rapidly ageing population and rising burden of complex non-communicable diseases, how well positioned is the current framework to support the launch of innovative and high-cost medicines in 2026?

I believe the framework still allows this, provided Hong Kong continues to preserve its competitive advantages. The city remains highly attractive to innovative pharmaceutical and R&D companies, particularly due to its strong intellectual property protection and well-established reputation in this area.

Hong Kong also benefits from a robust healthcare system, with highly trained physicians and respected medical education institutions, soon to be further strengthened by the establishment of an additional medical school. While price negotiations have undoubtedly become more challenging

than in the past.

If Hong Kong continues maintaining that robust healthcare system, good intellectual property protection, and high-quality healthcare service providers and practitioners, I believe the basic attractions remain fundamentally present.

Will closer Greater Bay Area integration bring more Chinese-developed medicines into Hong Kong, and how could this affect access and cost?

This is not only a Hong Kong issue. Chinese pharmaceutical research and development output has become the second largest globally, and Chinese Companies are increasingly looking overseas through different pathways, either via collaborations with multinational pharmaceutical companies or by expanding themselves internationally. We have already seen examples such as one of our member companies, BeiGene (now known as BeOne), which today operates as a truly global company.

We do not believe the discussion should focus on whether a medicine is Chinese or non-Chinese. What matters is whether it is genuinely innovative, meets high-quality standards, and delivers meaningful benefits to patients under a robust regulatory evaluation. The key considerations are transparency, fairness, a patient-oriented market, and respect for the value of medicines. Against that backdrop, the origin of a drug should not be the defining factor.

How would you characterise the rare disease access scenario in Hong Kong today?

The industry has long advocated for a dedicated rare disease policy in Hong Kong, as there is currently no orphan drug framework. Given Hong Kong’s very small population, named patient programmes have become a pragmatic solution, particularly where there may be only one or two patients with a given condition.

However, rare disease access extends far beyond treatment availability. Regulatory access through expedited pathways is one dimension, but when considering the full patient journey, there is much more to address. Awareness is the first challenge, followed by screening and early diagnosis. In Hong Kong, some patients experience prolonged diagnostic journeys, sometimes without knowing what condition they have. Diagnosis can take time, and locating clinicians with relevant experience is difficult – not due to any lack of capability, but simply because these conditions are rare.

Strong patient databases are therefore essential, potentially linked to global disease registries. We need to contribute more proactively and facilitate broader disease-level dialogue to improve screening and diagnostic pathways. While treatment via named patient programmes can be effective, the question remains how to accelerate diagnosis and ensure patients are identified earlier.

Importantly, named patient access does not equate to funding. Inclusion in mechanisms such as the Samaritan Fund or access to public funding remains extremely challenging. For patients, affordability and access to financial support are often decisive factors.

Ultimately, rare disease is not only about access to medicines – it is about whether we have a comprehensive ecosystem that supports rare disease patients from awareness and diagnosis through to treatment and funding.

As we enter 2026, what is the mood among your members, and what are your main priorities for the year ahead?

In early February, we co-organised with Real-world Data Application and Study Centre under Greater Bay International a seminar with the government on real-world data applications. This builds on the initiative we launched last year and will be our first event of 2026.

We are also working closely with Hong Kong government offices on the development of the Centre for Medical Products Regulation. If Hong Kong is to become an ICH member, the CMPR must operate to the highest standards, to ensure the certificates of pharmaceutical products issued by Hong Kong authority will be recognised by other authorities. The industry is committed to supporting the government through this process, while ensuring the CMPR evolves into an effective and efficient regulator.

At the same time, reimbursement remains a critical issue. Ensuring that innovation is effectively accessible to the healthcare system and patients is essential.

In clinical trials and real-world data, our focus is on generating more practical cases to establish clear and workable pathways. Additional proof-of-concept projects will help stakeholders become familiar with processes and build confidence in these routes. As pathways mature, we can better leverage Greater Bay Area research capacity to attract more clinical trials to Hong Kong.

Overall, our priorities remain clear: to drive expedient access to innovative healthcare solutions for Hong Kong patients, close collaboration with the government on CMPR development, strengthening

clinical trial activity, and advancing real-world data applications.

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