Lo Chung-mau â?? Secretary for Health of the Government of Hong Kong (2024)

My goal is to transform the region into a Health & Medical Innovation Hub

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Prof. Lo Chung-mau, Hong Kongâ??s Secretary for Health, delves into some of the key strategic initiatives for advancing Hong Kongâ??s healthcare and biomedical innovation. Key topics include the integration of the Greater Bay Area (GBA) for enhanced clinical trials, addressing the increasing needs of Hong Kong healthcare system, and leveraging international partnerships for global benchmarking. Lo emphasises, â??Seeing is believing,â?• highlighting the importance of firsthand experience to understand the vast opportunities within the GBA.

How has your previous experience equipped you for your current role and what are your priorities today as Hong Kongâ??s Secretary for Health?

It was with great honour that I assumed the role of Secretary for Health in 2022. This represents the third key area covered in my career at the University of Hong Kong. First, I worked as a liver transplant surgeon, where I worked on surgical innovation for the benefit of patients.

Then, I was deeply involved in healthcare reform in Mainland China, leading the University of Hong Kong-Shenzhen Hospital, an incredible hospital by any global standards. Over the 10 years I spent at that institution, it served as a major platform for piloting healthcare reforms.

Upon embarking on this third phase of my career as Secretary for Health I set forth three key missions. The first was to implement an evidence-based approach to overcoming COVID-19. Within

nine months, we transitioned to normalcy from the severe fifth wave in Hong Kong, ultimately lifting the mask mandate.

The second mission is to enhance and continuously improve healthcare services in Hong Kong. While we have an excellent and highly efficient healthcare system, it is crucial to keep pace with rapid advancements in medicine. Utilizing outdated treatments, even from just a decade ago, is not an option.

The third mission is to leverage Hong Kongâ??s high-quality healthcare services and our advancements in research and innovation to position Hong Kong as a leader in the GBA and beyond. With nearly 40 years of experience in the medical field, I firmly believe in leading rather than following advancements. For instance, in liver transplantation, we were the first to develop the right-lobe living donor liver transplant technique, significantly improving patient outcomes.

During my time at the University of Hong Kong-Shenzhen Hospital, we successfully combined Hong Kongâ??s healthcare management with the Chinese healthcare system to find an optimal healthcare management model, which was later adopted by the national government. Back in Hong Kong, my goal is to transform the region into a Health & Medical Innovation Hub, as outlined in the Chief Executive Policy Address in 2023. This vision was inspired by my experience at the University of Hong Kong-Shenzhen Hospital, and I believe the timing is perfect for this transformation.

How is Hong Kong overcoming the challenges of conducting large-scale clinical trials and securing market registration for medical products, given its relatively small population?

Historically, Hong Kongâ??s population of 7.5 million posed significant challenges for large-scale clinical trials beyond phase one. We could only contribute a limited number of candidates for multi-centre trials, making it unattractive for pharmaceutical companies to register their products here due to the small market size. However, two pivotal developments have changed this landscape.

Firstly, the Guangdong-Hong Kong-Macao Greater Area (GBA) initiative has fundamentally redefined our approach. Hong Kong is no longer working in isolation. Pharmaceutical companies conducting clinical trials here now have access to a potential market of 86 million people within the GBA. This integration, driven by national policy and championed by President Xi, has been in progress for five years.

Secondly, the GBA initiative addresses the registration system and pricing concerns. We are progressing towards higher integration and standardized practices between Hong Kong and Mainland China. While under â??one country, two systemsâ?•, the drug registration systems differâ??with the National Medical Products Administration (NMPA) in the mainland and the Department of Healthâ??s Drug Office in Hong Kongâ??a special measure now allows Hong Kong-registered drugs and medical devices used in public hospitals to be used within designated healthcare institutions operating in the GBA, even if they are not yet registered with the NMPA. This measure, endorsed by the Central Peopleâ??s Government, the NMPA, and other authorities, represents a significant advancement.

This initiative is already in effect. I was leading in its implementation. The University of Hong Kong-Shenzhen Hospital was the first pilot site for this measure, demonstrating how drugs registered and used in Hong Kong, but not yet in Mainland China, can be effectively utilized in the hospital setting in GBA. This innovative approach addresses both patient volume and market registration challenges, positioning Hong Kong as a key player in the medical innovation landscape.

How is the payment system managed for Hong Kong-registered drugs and medical devices used in the GBA, considering the different healthcare systems in place?

The process involves sourcing drugs from Hong Kong and importing them with a special license through customs for use in hospitals. The drugs are charged at cost under the National Health Insurance (NHI) of Mainland China, so Chinese patients do not rely on the Hong Kong financing system. This arrangement is part of a special measure to address the lag in the NMPAâ??s registration process. Many advanced drugs and devices used in Hong Kong are not yet registered in Mainland China, which previously led many mainland patients to seek these treatments in Hong Kong.

With the development of the GBA, there is a push to improve healthcare services, including access to advanced drugs and devices. The rationale is that if these medical products are safe, effective, and used in Hong Kong, they should also be available in selected healthcare institutions in the GBA. This measure ensures that Hong Kong citizens working and living in the GBA receive a similar level of care, and it significantly raises the healthcare standards in the region.

The pilot program began in 2021 at the University of Hong Kong-Shenzhen Hospital and lasted until July 31, 2021. It has since expanded to 19 hospitals, with 32 drugs and 31 devices now available. The process is controlled and cautious, allowing a green channel for these advanced medicines and devices specifically for the GBA. This initiative not only improves healthcare standards but also provides drug companies with a pathway to collect real-world data, which is crucial for formal registration with the NMPA.

We are also planning to develop a GBA International Clinical Trial Institute to further enhance our capabilities in conducting clinical trials and advancing medical innovation. This will facilitate the collection of real-world data from patients, helping in the formal registration process and ensuring that advanced medical treatments are available to those who need them.

How significant is the recent move in Hong Kong to accept just one international certificate of pharmaceutical product (CPP) rather than two? Was it a difficult decision to take?

The transition from secondary to primary evaluation is the ultimate goal of our regulatory authority, the Center for Medical Products Regulation (CMPR). The â??1+â?• mechanism is a critical intermediary step in this process. It provides a much faster route for new drug registration by eliminating the delays typically associated with attaining a second CPP.

This streamlined approval process accelerates the registration of innovative drugs and devices from both the Western world and Mainland China, where the biomedical industry is advancing rapidly. The â??1+â?• mechanism allows us to build the necessary expertise and talent pool, preparing us for primary evaluation.

Additionally, this period is being used to enhance our clinical trial facilities and capabilities. The GBA offers a significantly larger clinical sample capacity and market potential, which we are leveraging through the development of the GBA International Clinical Trial Institute.

The GBA International Clinical Trial Institute is expected to be operative before the end of 2024 and although you are clear on its synergetic role some stakeholders worry this could introduce additional bureaucracy. Why is a centralized body essential for this initiative?

When the government initiates a project, scepticism from vested interests is common. However, our role is to coordinate and facilitate, not impose. Currently, clinical trials in Hong Kong are managed in a fragmented manner by institutions like the Clinical Trial Center (CTC) at the University of Hong Kong and the Chinese University of Hong Kong. While these centres conduct trials, their scale and impact are limited.

Our goal is to coordinate on a much larger scale, leveraging the 86 million population in Mainland China. We are utilizing the Hetao Shenzhen-Hong Kong Science and Technology Innovation Cooperation Zone (HTCZ), which is a national policy directive. The Shenzhen Park work plan, issued by the Central Peopleâ??s Government State Council last August, explicitly aims to develop a GBA international clinical trial centre through Shenzhen-Hong Kong cooperation.

This initiative aligns with Hong Kongâ??s role in the 14th Five-Year Plan to become an international innovation and technology hub. Biomedical technology is a significant focus area. Hong Kong is well-positioned for this due to our excellent healthcare services, efficient healthcare system, and robust talent pool. The Hospital Authorityâ??s IT system, which integrates 43 hospitals and 11 million patient records, exemplifies our advanced infrastructure.

Although there have been complaints about data access, we are currently addressing these issues. By integrating and coordinating efforts within the Hetao area and beyond, we aim to create a more impactful and efficient clinical trial environment, benefiting both academia and industry.

Our goal is to facilitate all aspects of clinical trials, including providing resources. Some critical elements require government involvement to function effectively. Firstly, we need to manage the cross-border movement of biosamples and clinical data. Effective coordination with the Shenzhen government and the Central Peopleâ??s Government is essential for the seamless transfer of data and samples across borders, which is crucial for running clinical trials in the GBA.

We will establish central data banks, biobanks, and possibly core laboratory facilities in the Hetao area. These facilities will ensure the security and standardization of data and samples. By having a core facility at the border, we can facilitate the coordination and secure management of these crucial elements.

In addition to coordination, we are integrating public and private hospitals. Currently, university Clinical Trial Centers (CTCs) must seek approvals from multiple research ethics committees/ institutional review boards for cross-cluster clinical research, which can be cumbersome. We are implementing a centralized institutional committee review board for the 43 public hospitals managed by the Hospital Authority in Hong Kong to facilitate single application and single approval of cross-cluster clinical research.

With one protocol, one data bank, and one computer system, researchers can access necessary data to prepare protocols and plan new studies. This integration will allow drug companies to access demographic and patient data, facilitating the planning and execution of clinical trials. This centralized system is already being piloted with the science park, providing a robust framework for future clinical trials.

Given the strain on healthcare resources, how do you plan to address the potential shortage of trained personnel for clinical trials in Hong Kong?

Addressing the shortage of trained personnel is essential, and our approach involves both local training and international recruitment. Hong Kong has a strong track record in this regard, supported by our two leading medical schools. The GBA International Clinical Trial Institute will play a crucial role as a training centre for clinical trial personnel. We are finalizing discussions with the Shenzhen Municipal Government and the Shenzhen Health Commission to establish the GBA International Clinical Trial Center, as outlined in the Shenzhen Park Work Plan. This collaboration between Hong Kong and Shenzhen is integral to our national strategy.

Considering the differences in medical education between Mainland China and Hong Kong, how do you manage these variations in the context of clinical trials and medical practice?

The medical curriculums in Mainland China and Hong Kong differ, with programs ranging from 5 to 8 years in China. However, we have accredited 17 of their medical programs for special registration in Hong Kong. Graduates from recognized institutions, such as Shanghai Fudan University and Sun Yat-sen University, can practice in public healthcare institutions in Hong Kong under special registration. After working satisfactorily for five years and obtaining a specialist qualification, they will be granted full registration. This approach respects the global diversity in medical education systems.

In clinical trials, we leverage Hong Kongâ??s high standards of quality with the patient volume available in Mainland China. Two key factors make this an opportune time for establishing an innovation hub: the five-year progress of the GBA initiative and significant improvements in Chinaâ??s healthcare system due to ongoing reforms. Ten years ago, collaboration would have been challenging due to the reliance on drug sales for income in Mainland hospitals. Doctors had to sell drugs to supplement their low salaries, which was not conducive to evidence-based healthcare.

However, with the zero-markup policy on medicines implemented about nine years ago, doctors no longer rely on drug sales for income. This shift has enhanced professionalism and evidence-based practice. Now, doctors prescribe drugs based on their efficacy and necessity for patient health, creating a more conducive environment for clinical trials.

Many years ago, the GBA concept seemed more theoretical than practical. While conducting clinical trials is promising, what is the ultimate goal of this initiative, and how do you plan to elevate the entire ecosystem towards biomedical innovation?

The GBA initiative offers a tremendous opportunity to transform the biomedical innovation landscape, particularly for rare diseases. Take Osteogenesis Imperfecta (OI) as an example, a genetic disorder causing brittle bones. In Hong Kong, with our low birth rate, only two or three cases are seen annually, making research and training difficult. Drug companies typically arenâ??t interested in such small numbers.

However, at the University of Hong Kong-Shenzhen Hospital, we established the only centre for Osteogenesis Imperfecta in southern China, seeing 200 to 300 cases each year. We regularly perform surgeries to reinforce these childrenâ??s bones, providing a wealth of data and clinical experience. This scale is invaluable for research on rare diseases.

Leveraging Hong Kongâ??s resources and the larger patient base in the GBA, we can significantly enhance research and development efforts. Rare diseases are never rare in mainland China as the large population means more cases to study and treat, creating a gold mine for research, education, and training. The advancements in healthcare infrastructure and policy support better diagnosis and treatment, offering a robust environment for clinical trials and biomedical innovation.

In Mainland China, the perception of rare diseases is evolving, and the governmentâ??s zero-markup policy on medicines has shifted focus towards evidence-based healthcare. This environment is conducive to high-quality clinical trials and the development of new diagnostics and therapies. By integrating Hong Kongâ??s high standards with the patient volume in the GBA, we can create a thriving ecosystem for biomedical innovation, benefiting both researchers and patients.

During your recent visit to the WHO conference in Switzerland, you also visited the headquarters of leading pharmaceutical companies Novartis and Roche. Taking this as an example what has been the feedback from companies about the GBA initiative?

During my discussions with Novartis and Roche, it became clear that they were not yet fully familiar with the GBA concept. There are some misunderstandings and misconceptions about Hong Kong and the GBA. Firstly, the scope and significance of the GBA as a national initiative, which has been in place for five years and includes nine cities in Mainland China as well as Hong Kong and Macau, are not well understood. This initiative offers significant opportunities for cross-border collaboration and mutual enhancement of healthcare standards.

There is a concern among some in the Western industry that the GBA might diminish Hong Kongâ??s unique position. However, this concern is unfounded. If you are strong, you donâ??t fear being overshadowed; instead, you help elevate others while creating a bigger pie for everyone. Hong Kong is a leader in medicine and healthcare, and we will continue to lead. The collaboration with the GBA is a win-win situation. Our experience with the University of Hong Kong-Shenzhen Hospital demonstrates how we can drive reforms and improve healthcare standards while benefiting our own medical community. Now that I am back in Hong Kong, our goal is to continue leading the way, leveraging our facilities and expertise to help the entire GBA progress. This partnership ensures that we all move forward together, making significant impacts and achieving mutual success.

Iâ??d like to stress the importance of firsthand experience. Iâ??ve invited representatives from Roche and Novartis to visit Hong Kong, the Hetao area, and the GBA to see the opportunities themselves. This initiative serves as a gateway for global pharmaceutical industries to access Hong Kong, China, and the GBA through a green channel, while also enabling the Mainland biomedical industry to reach global markets. Hong Kongâ??s unique position, supported by the motherland while engaging with the world, offers both global and China advantages. This is an ideal time to advance this initiative. The ultimate goal is twofold: improving healthcare for our people and enhancing our economy.

During your visit to Geneva you discussed regulation and pre-qualification with the WHO. Can you elaborate on Hong Kongâ??s efforts to achieve ML3 and ML4 status and how this aligns with your broader goals for biomedical innovation?

During our visit to Geneva, we met with WHO experts on regulation and pre-qualification, including Dr. RogÃ©rio Gaspar, the director. He was very supportive and encouraged us to pursue WHO Global Benchmarking Tool maturity level (â??MLâ?•)3 status first. Achieving ML3 and eventually

ML4 is integral to our strategy to enhance Hong Kongâ??s global standing in biomedical innovation.

Countries like Singapore and Korea have achieved LM4 in recent years, and Saudi Arabia joined them last year. This status is crucial for advancing vaccine manufacturing and other specialized areas. Dr. Gaspar emphasized Hong Kongâ??s unique position under the â??one country, two systemsâ?• framework. While we are part of China, our international orientation makes us an ideal bridge for China to engage with the global benchmarking system.

Our objective is to leverage this unique position to propel our biomedical innovation efforts. Achieving LM4 would be prestigious and highly beneficial for Hong Kong, especially in the realm of vaccine manufacturing. The expansion of the Hong Kong-Shenzhen Innovation and Technology Park will further support these initiatives. We are committed to this goal and will continue to collaborate with international partners to make it a reality.

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