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For pharmaceutical companies, the HK-GBA early access program could serve as a valuable testing ground in GBA for their market launch strategies in mainland China

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Novartis, one of the world's largest biopharma companies, has secured approval and market access for two of its most advanced cell and gene treatments in Hong Kong. The firm's territory head, Derek Chang, highlights how early access to innovative therapies in the Hong Kong-Greater Bay Area (GBA) can unlock winning opportunities for mainland China, Hong Kong's current output and potential as a clinical trials hub, and the areas in which its healthcare ecosystem can be further strengthened.

What steps in your career have led you to this position?

I began my career over 20 years ago and have worked primarily in mainland China. I started out as a healthcare consultant at McKinsey in Taiwan and after a single year moved to Shanghai. I was eight years in total at McKinsey and spent one year on a rotational program in Germany. Then in 2011, I moved to my first pharma industry role at Roche in Shanghai as a strategic planning director and area sales director before moving back to Taiwan in 2014 as the affiliate’s BU head in charge of Oncology. After three years in that role, in 2017 I joined AstraZeneca in Shanghai as a franchise head for diabetes before starting my journey at Novartis in 2019 as the China BU head in charge of Ophthalmology in Shanghai. After three years in that role, in June 2022 I was offered my first general manager role for Novartis in Hong Kong. Currently, I am also a board member of the Hong Kong Association of the Pharmaceutical Industry (HKAPI) chairing the Great Bay Area (GBA) task force.

What is the benefit for multinational companies like Novartis establishing an affiliate in Hong Kong and not simply working via a distributor, given the modest size of the local market?

Hong Kong is a significant market based on market value. As far as I know, Hong Kong ranks in the top 6 markets in the Asia Pacific (APAC) region by sales for many multinational pharmaceutical companies. Hong Kong not only operates under the 'One Country, Two Systems' principle, which sets it apart from mainland China, but it also holds strategic importance for mainland China and the APAC region.

At present, drugs that are approved in Hong Kong but not yet registered in mainland China can be used in 19 hospitals within GBA, including eleven 3A hospitals. The GBA policy aims to promote drug availability by expanding the list of new drugs and expanding coverage to additional hospitals to benefit the overall population of 87 million in the GBA.

For pharmaceutical companies, the HK-GBA early access program could serve as a valuable testing ground in GBA for their market launch strategies in mainland China. Real-world data (RWD) can be collected to support treatment consensus and medical guidelines prior to a full-scale launch in mainland China. The HKAPI has also suggested this RWD could be utilized as a supplement to support drug registration or national reimbursement enlistment in mainland China, particularly in areas such as rare diseases or children's drugs where limited clinical trials have been conducted.

Furthermore, the government has positioned Hong Kong as the leading biomedical hub in Asia and is actively promoting the launch of advanced therapy products (ATPs). We are honoured to have obtained the first two ATP approvals, specifically CAR-T therapy and gene therapy. By leveraging our office in Hong Kong with local expertise, we have successfully introduced these cutting-edge therapies to the Hong Kong market, benefiting not only patients in Hong Kong but also those in the GBA and other Asia markets where these advanced therapies have not yet been locally launched.

What objectives were laid out for you upon taking this position, and how many have you been able to achieve in your first year on the job?

Based on the latest market data from IQVIA, Novartis is the second-largest pharmaceutical company in terms of sales in Hong Kong, excluding over the counter (OTC) and vaccine products. With approximately 100 innovative medicines registered, our products benefit around one million

patients each year. We remain committed to accelerating our research and development efforts to deliver breakthrough treatment for patients. Currently, we have 40 ongoing clinical trials spanning phase I to phase IV, and we plan to submit over 50 applications for new drugs, new indications, or line extensions within the next five years.

Novartis is always aiming to promote its advanced therapies to patients in Hong Kong. This commitment aligns with the government's call to prioritize the advancement of life sciences, healthcare, and the promotion of the region as an international biomedical hub. We are happy to lead the way on this front with our revolutionary cell and gene therapies.

How smooth has the regulatory pathway been for these advanced therapies?

The regulatory approval for ATP is a separate pathway, although we still need certificates of pharmaceutical products (CPPs) from two separate regulatory bodies, such as the US FDA or EMA in Europe, before a therapy can be approved here.

We understand, there are ongoing discussions to accelerate the approval timeline for drugs by considering the experience of neighbouring areas as a point of reference. One example of this is the implementation of rolling submission in Macau [another 'Special Administrative Region' of China which neighbours Hong Kong – Ed.] It allows drug developers to submit the application dossier for review while other supplementary documents or the CPP can be submitted later before final approval. This process enables patients to receive the products much earlier, typically just a few months after US FDA approval.

I would suggest that the Hong Kong regulatory authority consider adopting the rolling submission approach. This means that the drug dossier can be submitted for review after receiving the first CPP. Once the second CPP approval is completed, or other equivalent requirements have been fulfilled, the product can be made available to patients. Currently, patients in Hong Kong have to wait approximately 1.5 years after the drug is available to be used in the first approved country.

To promote Hong Kong as an international biomedical hub and position it as the first region to approve the drug in the Asia Pacific, it is crucial to expedite the entire process.

How prepared are the Hong Kong healthcare system and government payers to adopt advanced therapies of the like of the cell & gene ones?

As a pharmaceutical company, one of our roles is to manufacture the product and deliver it to patients, but between these operations there are many steps, and even more with these advanced treatments. We must make sure that the patient is medically eligible to receive the therapy, including a range of testing, verification, and operations, but the question is who will undertake this task?

At Novartis, we co-created with the leading hospitals the steps for medical eligibility to see if the patient can receive the treatment. Right now, CAR-T is a third-line treatment, so if a patient fails the first two lines they will be given it. This means most of the time we are treating patients with very aggressive cancers in urgent medical need. Thus, any delays in the process are unacceptable. The co-created process has been progressing well and we have been able to make a significant difference in the lives of patients, often saving them from life-threatening situations.

Once a patient is deemed eligible for CAR-T therapy, their cells are extracted and sent to the US to manufacture the final product. Do you foresee this lengthy process shortening in the future?

We are currently developing the next-generation CAR-T platform, that will serve as the foundation for various investigational CAR-T therapies. This platform can reduce the manufacturing time compared to traditional methods. The American Society of Hematology has released data which shows the manufacturing time dropping from 9-10 days all the way down to less than two days. The door-to-door time, which refers to the time from the pickup of the patient's cells to the delivery of the final product back to the hospital, is anticipated to be around a week. This is a significant improvement compared to the current door-to-door time of 20 or more days. Thus, it would make sense to place a production site closer to Asia to further shorten the transportation time.

Besides its incredible footprint in advanced therapies, in which therapeutic areas has Novartis been historically performing most strongly in Hong Kong?

Our roots in Hong Kong can be traced back to 1947, and we have been serving the Hong Kong community for 76 years. The major therapeutic areas cover Cardiovascular, Immunology, Neuroscience, Solid Tumors, and Hematology.

This year, we won the "Swiss – Hong Kong Innovation Award" presented by Dr. Bernard Chan, Acting Secretary for Commerce and Economic Development, and Mr. Juerg Burri, Ambassador of

Switzerland to China in the Swiss Business Excellent Night. With more than 250 Swiss companies in Hong Kong and over 20 entries in contention, we have been awarded first place thanks to our innovative therapies. Our xRNA platform, which assists patients with hyperlipidaemia in managing their cholesterol levels, wins the most attention from the audience.

The pricing of innovative therapies in Hong Kong entails a tendering process. How have the negotiations been with such a strong portfolio approved here?

The tenders here do not just take pricing into consideration but look at the full benefits that a drug can bring to patients. There is a consensus point reached between the government and the pharmaceutical companies.

I would say that Hong Kong has one of the best co-payment funding models within the territories I have worked in. In the Hong Kong system, the co-payment amount is calculated based on the annual disposal financial resources (ADFR) of the patient. The maximum co-payment for patients is set at 20 percent of their annual disposable income, while lower-income earners are only required to contribute five percent or less. This means people of all levels of income levels receive the same level of healthcare, from the affluent to the underprivileged, and there is a balance reached between the government payers and patient benefits.

Furthermore, approximately 30 percent of the population is using private insurance, and this is a growing trend. It is optional and in many cases is provided by an individual’s employer. This will open up new opportunities for patients to access innovative therapies.

A big part of introducing innovation early is through clinical trials. Is Hong Kong a good place to conduct clinical research in your view?

Yes. Hong Kong has many world class professors and doctors with leading facilities and environments within universities and hospitals. Therefore, we have over 40 ongoing clinical trials being conducted in Hong Kong. Specifically, there are more than 20 phase I and phase II clinical studies focusing on our target disease areas.

During a visit by Prof. Sun Dong, Secretary for Innovation, Technology, and Industry, to Novartis Headquarters in Basel, Switzerland, we engaged in discussions regarding additional investment and collaboration opportunities for research and development in Hong Kong.

The Greater Bay Area together with Hong Kong, particularly in clinical trials and access to innovation can help to increase the population pool to something close to 87 million people. Do you see potential there?

The Guangdong Medical Products Administration (GDMPA) has approved five Novartis products, the highest number of approved drugs among pharmaceutical companies, to be used in the GBA. As the Chair of the GBA task force in HKAPI, I had the opportunity to bring our board members to visit the GDMPA and engage with the Vice Directors responsible for GBA policies. This visit has revealed the immense potential that exists in the region.

The population of 87 million in the GBA is in urgent need of innovative therapies, which we are well-equipped to provide. Additionally, the real-world data generated in this region is unique, as no other areas in mainland China have this level of experience in utilizing such therapies. Consequently, this data is crucial and critical for Chinese patients. I would like to urge the central government to recognize the value of this data because this can truly make a difference in the lives of more Chinese patients, particularly in the areas of rare diseases and children's drugs.

Novartis has a strong footprint in Hong Kong being placed amongst the largest medicines company operating in the territory. What has been done right to reach this point?

We have worked as a team to bring high-technology innovation to Hong Kong, and I would say it is a place that really values advanced therapy products and has excellent market access compared to other territories that do not get this support. This is because the healthcare infrastructure and system in general works well in Hong Kong and promotes innovation.

Secondly, I would say my colleagues are experts in their fields and have long-term connections with the relevant stakeholders, such as hospitals, medical associations, and patient organisations.

Thirdly, it is a science-driven market and once we have the results of the latest clinical studies, we are very quick and transparent to educate the relevant stakeholders and share our information. This transparency builds trust, which is a value at the top of the list for Hong Kong locals.

What would you say are the key improvements needed for Hong Kong to advance its healthcare in the future?

We are all aligned in our support for Hong Kong's goal of becoming an international biomedical hub. However, the speed of drug approval and market access can be further accelerated.

No matter whether one CPP requirement or a two CPPs nation system is ultimately decided, implementing a rolling submission process is critical to expedite the overall approval timeline. The steps towards reimbursement that exist today are clear, but the steps and processes can be simplified and streamlined as it is important that patients receive life-improving or life-saving medicines rapidly.

Finally, a challenge facing Hong Kong more broadly is a lack of healthcare professionals. Many Hong Kong nationals are leaving to work abroad and not returning. We need to keep them here or attract people to the region to work.

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