

Consulate General of the Kingdom of The Netherlands Guangzhou

Guangdong's Life Sciences and Health Sector Scan

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JENESY WANG

Consulate General of the Kingdom of the Netherlands in Guangzhou

NICO SCHIETTEKATTE

Embassy of the Kingdom of the Netherlands in Beijing

This report was written by:

Ms. Jenesy Wang, Commercial Officer at the Consulate General of the Kingdom of the Netherlands in Guangzhou

Mr. Nico Schiettekatte, Counselor for Health, Welfare & Sport at the Embassy of the Kingdom of the Netherlands in Beijing

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I. Introduction and overview of Life Sciences and Health (LSH) sector in Guangdong

Life Sciences and Health is one of the top sectors for cooperation and exchange between the Netherlands and China. The Consulate General in Guangzhou together with the Embassy of the Kingdom of the Netherlands in Beijing identified the Guangdong province as an important province that matches the ambitions, know-how and high-end products & services of the Dutch sector. At the same time, these opportunities have so far not been made sufficiently visible, partly due to COVID related circumstances. The following report therefore provides the Dutch LSH sector with an overview of the current status, relevant developments, trends, challenges and opportunities in the LSH sector in Guangdong. Several Dutch healthcare organizations are already active in Guangdong, in a broad variety of activities. Think of organizations like Philips or Buurtzorg, to name but a few.

Guangdong is a coastal province located in southeast of China, adjacent to Hong Kong and Macau. It is the province with the highest GDP in China for 33 consecutive years and reached 1.74 trillion Euro in 2021. To compare, Guangdong's GDP in 2021 was higher than the GDP of Italy, Canada or South Korea. However, similar to many provinces in China, economic developments are concentrated in a few cities. Shenzhen, Guangzhou, Foshan, Dongguan are the top 4 cities in terms of GDP ranking. Dongguan, which is ranked the 4th place, has twice the GDP of Huizhou, ranking the 5th, in 2021. The population of the Guangdong province amounted to over 126 million according to the 7th population census in 2021. It is the most populous province of China, with 8.58% of the total population being 65 years or older.

Both the biopharmaceutical and the health industry are the strategic pillar industries in Guangdong. It covers biopharma, chemical drugs, traditional Chinese medicine, medical devices, healthcare services and elderly care sectors. Through years of development, Guangdong has been showing its growing capacity in the sector. According to the Department of Industry and Information Technology of Guangdong, until 2019, the revenue of biopharma and health industry has exceeded 65.5 billion Euro, of which the biopharma industry's revenue surpassed 32.75 billion Euro, and the number of valid invention patents was 9702. It is estimated that by 2025, the revenue of Guangdong's biopharma and health industry will reach 131 billion Euro. One can expect that the number of valid invention patents will increase accordingly. With a number of well-developed bio-parks, three national level clinical research centers, two provincial level laboratories, many research institutions and innovative companies, Guangdong has formed several industrial clusters in the region.

In terms of healthcare services, the healthcare expenditure of Guangdong has been increasing year by year. The total healthcare expenditure of Guangdong province reached 80.48 billion Euro in 2019,

accounting for 5.7% of the province's GDP. It has increased by 18.2% compared to 2018. The number of healthcare institutions, number of beds, and number of medical staff are also increasing year on year. The Guangdong government has setup goals and measures to further improve the quality, affordability, and accessibility of healthcare services.

II. Purpose

The purpose of this report is to provide an overview of Guangdong's (high end) LSH sector and identify opportunities for future cooperation and exchange with different Dutch stakeholders, such as Dutch governmental agencies, entrepreneurs, academia and foundations/non-governmental organizations.

III. Thematic focus

Based on current developments and trend of LSH sector in China, and considering interests from the Dutch LSH sector, several specific themes are chosen to be discussed in detail as below.

A. General Health Policies: Healthcare Reform

Healthcare reform remains the core topic when discussing about LSH sector in China. Although the whole reform policies are formulated by government at central level, implementation at provincial level can vary according to local circumstances. The Guangdong government released an announcement outlining the priorities for Guangdong's healthcare reform in Aug 2021 which aligns very well with Dutch know-how and interests.

Improving healthcare affordability has been the one of the most important objectives in the healthcare reform. Diagnostic Related Group (DRG), Diagnosis Intervention Packet (DIP) system and Volume based Procurement (VBP) are some of the major tools in the medical pricing reform. VBP have been making a large impact in the healthcare industry and it has become the new normal. VBP are conducted at two levels, national and regional (provincial and municipal). As the largest drug consumption province, Guangdong has been leading an alliance with over 10 provinces to procure drugs and medical consumables at largely reduced prices with bulk volume. The third round of Guangdong VBP was completed in Dec 2021. The average price cut for drugs is 27.5% on top of the previous reduced prices. Some of the high value medical consumables have steeper price cuts. For example, ultrasonic scalpel has an average price cut of 70.11%.

Another important objective of healthcare reform is to improve the healthcare accessibility. Improving the distribution of high-quality medical resources is set as one of the priorities. Guangdong aims to develop

50 high level hospitals and international medical centers in the discipline of respiratory, nephrology, oncology, precision medicine and cardiovascular healthcare.

Digitalization is also a priority of Guangdong's healthcare reform. Internet + Medical Service is the national strategic priority, and Guangdong is leading in this aspect. According to the Guangdong Health Commission, smart healthcare services has covered all of Grade III¹ hospitals and 90% of Grade II hospitals. Patients can use online platforms on their mobile phone to make appointments for consultation and examination, receive examination report, process online payment, collect drugs, etc. The pandemic has also been speeding up further on digitalization developments in health & care. Until Nov 2021, already 251 internet hospitals in Guangdong were providing online consultation, which made healthcare service accessible for residences in rural areas. Some of the internet hospitals are able to provide one stop medical service, from online diagnosis and treatment via video and pictures, online payment to drugs distribution. Based on current achievements, Guangdong plans to further develop digitalization by employing technology such as remote healthcare, smart healthcare service, AI and 5G application. These developments provide opportunities in policy exchange and business between the Netherlands and Guangdong.

In the context of healthcare reform, drugs and medical device companies that are in the China market need to set up a more comprehensive market and pricing strategy, as well as managing cost control in order to adapt to the VBP. It is no doubt that digitalization will continue to be developed as it is not only improving healthcare accessibility, it also helps to provide higher quality of medical services. Technologies and products related to remote diagnosis and remote treatment, health monitoring, smart healthcare, smart health management and AI will have the opportunity to tab into the market.

B. Medicines and Medical Technology

1. The Development of Medicines and Medical Technology in Guangdong

Guangdong's medical technology sector is a competitive market. Although a large percentage of the highend medical devices are occupied by imported products, more and more competitive local companies have emerged in recent years. With its 27 listed medical device companies, Guangdong has the highest number of listed medical device companies amongst all provinces and regions in China. Until April 2019, Guangdong already had 3743 medical device companies, which also ranked the first in China. In terms of

¹ China has a 3 graded hospital classification system. It is classified based on function, equipment and technology. Grade III is the highest grade, with the most comprehensive function, highest capability to provide medical care and perform medical education and scientific research.

segment, Guangdong is particularly strong in imaging, especially in color ultrasound. *Mindray* and *SonoScape* are the major players in this field. They are both Shenzhen headquartered companies that established research and development centers and sales office overseas, including in the Netherlands. While Shenzhen is strong in imaging, Guangzhou's advantage is in the In Vitro Diagnosis (IVD) segment. *DaanGene* and *Hybribio* are major players in molecular diagnosis and *Wondfo* is leading in Point of Care Testing (POCT) segment. All of them are China stock market listed companies and have been exporting products overseas. In addition, *Wondfo* has established a research and development center in the U.S.

Compared to medical technology, Guangdong's research and development of new drugs is lagging behind. There are five Guangdong pharma companies that entered the 2019 China Top 100 Pharmaceutical Industry List (published by China Pharmaceutical Industry Information Center). For these five companies, the chemical drugs approved under the new registration classification which was started in 2017 are mostly generic drugs. Ilaprazole Sodium from *Livzon Pharmaceutical Groups* is one of the few improved innovative new drugs that is approved within these top pharma companies. Guangdong is the province with the largest pharmaceutical sales market in China, and it has always been an important province for pharma companies. However, in recent years, Guangdong's research and development of new drugs are far behind Jiangsu. Indeed, Jiangsu has been working closely with nearby regions including Shanghai and Zhejiang province and has formed the synergies effect in regional development. Also, compared to Jiangsu, Guangdong does not have a well-developed Active Pharmaceutical Ingredient (API) industry, and has a lower number of Contracted Research Organization (CRO) institutions. In order to change the situation, Guangdong has been carrying out supporting policies. These policies are mainly implemented by the bio-parks in the region.

The establishment of bio-parks aim at promoting the synergy effect in the region, and at helping the biotechnology companies to leverage the regional policy, infrastructure, and the eco-system to start, grow and expand their business. The focus areas and supporting scheme of each bio-park vary. Taking Guangzhou Knowledge City as an example, below are some of the supporting schemes and their implications for biomedicine companies in the Park, including benefits for Dutch stakeholders:

Supporting Scheme	Implication
For projects that have a leading role in the biomedical industry, support will be given from 10% - 30% of the total investment in fixed assets, with a maximum of 65.5 million Euro for a single project.	This is targeting at very high investment projects. Such a high investment amount is usually a large investment in fixed assets, and the product must be a high profit biomedical product or high-end medical device.

For the world's top 500 companies, the world's top 50 pharma and medical device companies, unicorns and companies with outstanding innovation capabilities, independent legal person headquarters, R&D centers, or newly settled international companies in the region and well-known laboratories will be given up to 1.97 million Euro as subsidy.	To attract global companies to establish R&D center and startup and SME with unique technologies and advantages to setup headquarters in the Park.
For innovative drugs or improved new drugs that have obtained approval from National Medical Products Administration ² (NMPA) and are being industrialized in the Park, if they have invested more than 1.31 million Euro in clinical trials, subsidies up to 40% of the clinical trial cost will be granted (a cap will be applied).	It is expected to draw more research institutions for innovative drugs at pre- clinical stage to enter the Park.
For Marketing Authorization Holders (MAH), who authorizes contract manufacturing organization (CMO) to produce a medical product, the MAH will be subsidized at 5% of the actual transaction of the manufacturing contract value, with a maximum of 655 thousand Euro, and up to 1.31million Euro per year. CDMO/CMO who conduct production will be subsidized with 20% of the manufacturing cost at a maximum of 1.97 million Euro for each product, and up to 3.93 million Euro per year.	This is to encourage research institutions and CDMO/CMO to utilize the MAH policy, improve the allocation of resources, optimize of production capacity and improve the efficiency of a product from research to industrialization.

Source: 广州知识城促进生物医药产业高质量发展十条 (mofcom.gov.cn)

² Former China Food and Drug Administration

2. Preferential Policies in Greater Bay Area

To promote the collaboration amongst Guangdong, Hong Kong and Macau, and fully leverage the composite advantage of these three places to further promote the economic development, China central government has formed an economic area - Guangdong-Hong Kong-Macao Greater Bay Area (GBA).



GBA consists of two administrative regions, Hong Kong and Macao and nine municipalities of Guangzhou, Shenzhen, Zhuhai, Foshan, Huizhou, Dongguan, Zhongshan, Jiangmen and Zhaoqing in Guangdong Province.

Under this GBA initiative, the Chinese government has set up plans that open up the market for different sectors. In November of 2020, the State Administration for Market Regulation leading other relevant departments issued the Work Plan for Regulatory Innovation and Development of Pharmaceutical and Medical Device in GBA. Under this Plan, imported drugs and common medical devices that are approved to be used in Hong Kong and Macau, could be used in designated hospitals in GBA without NMPA registration. The designated hospitals need to be invested or operated by Hong Kong or Macau medical service providers. Starting from one pilot hospital in Shenzhen, the designated hospital list has expended to five hospitals, including two in Guangzhou, one each in Shenzhen, Zhuhai and Zhongshan. Until September 2022, there have been 20 imported drugs and 13 imported medical devices approved to use this policy in the designated hospitals.

Detailed criteria and procedures for application can be found in Annex B.

Besides the Work Plan which covers the whole GBA, there are more policies being drafted targeting at municipal level to enhance the effect of the GBA initiative. The National Development and Reform Commission and the Ministry of Commerce released an opinion on relaxing market access in Shenzhen as part of efforts to further open up the GBA on 26 Jan 2022. Regarding the medical and health sectors, the

document called for relaxing restrictions on market access for pharmaceuticals and medical devices, pilot trials of prescription drug online sales, as well as optimized approval, and access services for human genetic resources. One point which worth noticing is about supporting Real World Data application in the full life cycle clinical evaluation for local drugs and medical devices in Shenzhen, and further accelerate the process for the launching of new medical products. Focusing areas on clinical evaluations includes medical products in urgent clinical needs, rare disease treatment, AI medical algorithms, precision medicine, and traditional Chinese medicine. Further details and action plan regarding this opinion is pending to be released. One can expect that under the GBA initiative, more opening up policies in this region will follow in the near future.

3. Investment Trend in LSH sector

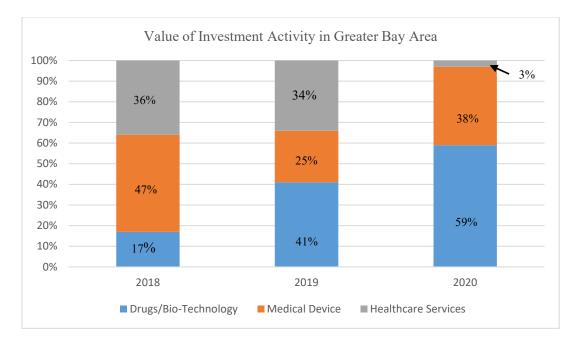
Although COVID has brought great challenges to the economy, the investment environment of LSH in China has been showing recovery since 2020. The three important regions for private equity and venture capital in LSH sector in China are the Yangtze River Delta, the Greater Bay Area and the Beijing-Tianjin-Hebei Region. Below table shows the top regions that attracted the investment in the LSH sector in China from 2018-2020. Guangdong ranked the fourth among all regions in China.

Province/City	Total Value (USD mn)	Total Volume
Beijing	10,303.1	376
Shanghai	10,223.6	467
Jiangsu	5,465.6	340
Guangdong	3,852.5	308
Zhejiang	3,567.9	217

Table: Regional investment activity by value and volume 2018-2020

Source: Deloitte: 2021 China LSHC M&A Market Whitepaper

Looking into GBA, from 2018 to 2020, there is a clear trend that the investment in drugs and biotechnology has been increasing steadily. Investment in medical devices experienced a 38% rise in 2020. Whereas this trend might have been caused by the COVID 19 pandemic with vaccines, drugs and COVID 19 related innovative technologies being the hotspots for R&D and investment in the LSH sector, this trend is expected to extend well beyond the post-COVID era providing several opportunities to Dutch stakeholders.



Source: Deloitte: 2021 China LSHC M&A Market Whitepaper

4. Opportunities for Dutch LSH Companies

With the raise of the domestic medical products, the maturity of the supply chain, and the promotion of national policies such as medical reform and support for domestic products, import substitution is going to be the trend in the upcoming years. Many large foreign LSH companies in China are trying to localize their production in order to compete with domestic products at a level playing field. On the other hand, there are multiple policies in the LSH sector to encourage the R&D of innovative medical products. Many Chinese companies have been actively introducing foreign innovative medical products and developed various cooperation models. Some of the listed pharma companies in Guangdong, such as *Akesobio* and *Salubris* have been devoted in R&D of innovative drugs for many years and established R&D centers in both China and overseas. In recent years, they are actively introducing overseas innovative medical technologies. For example, *Link Health Group*'s license in + CRO model has proven to be viable. *Link Health Group* has set up a subsidiary in Amsterdam and they have been collaborating with companies from the U.S., Canada and Europe.

That being said, Dutch companies with truly innovative medical products/technologies will have a better chance to step into the Chinese market, in particular in the GBA/Guangdong region. Dutch companies who established entity in China could consider localizing their production. With the MAH system in place, foreign companies collaborating with local CMO for manufacturing could be considered as

domestic products without licensing out. Based on the discussion above, popular fields for foreign medical products/technologies in the China market includes cardiovascular, diabetes and other chronic diseases and aging-related diseases, oncology, immunology, COIVD 19 related technologies, precision medicine, and cell and gene therapy. In addition, for Dutch medical products that are already being used in Hong Kong and Macau, the GBA initiative opens up another channel for entering the China market.

C. Long term care and elderly care

1. Overview of elderly care industry in Guangdong

According to international standards, Guangdong has entered the phase of an aging society since 2013. However, according to the 7th population census in 2021, the percentage of population over 65 is particularly low in a few cities. These are Shenzhen (3.22%), Dongguan (3.54%) and Zhongshan (5.98%). Comparatively, tier 3³ and tier 4 cities have higher percentage of population over 65, for example Chaozhou and Shaoguan are having over 13% of population aged over 65.

Under the 14th Five Year Plan, the senior care service strategy will focus on the development of community and home-based care, and integration of elderly care service and medical care. Guangzhou is exploring a model that is a combination of these two. In October 2020, Guangzhou government issued an action plan to facilitate the construction of the Guangzhou comprehensive elderly care service center – Yikang Center (顾康中心). Yikang Center is an inclusive elderly care center that serve the elderly in the local community. The function of Yikang Center could include full-time care, day care, elderly carteen, medical and nursing services and leasing of elderly assisting equipment. They are operated by private institutions or companies and subsidized by government. Depending on actual function and model of each Yikang Center, the subsidies could be granted in aspects including rental, medical and nursing services, bed for full-time care, Long-term Care Insurance and etc. The target is to build at least 1 Yikang Center in each sub-district (街道) in Guangzhou. Until Sept 2021, Guangzhou already built 179 Yikang center. Although there are ongoing debates as to whether an Yikang Center could sustain without subsidies from the government, this type of model helps the private sector to reach the elderly in the community, build up their reputation, explore more business opportunities, and train a large number of professionals in this field.

Besides the Yikang Center model, which depends on government subsidies to a certain level, the GBA initiative has opened up other opportunities for mid to high end elderly care services. Compared to

³ Tier 3 or 4 cities are the less economically developed cities. For further explanation, please refer to: <u>https://en.wikipedia.org/wiki/Chinese_city_tier_system</u>

Guangdong, Hong Kong and Macau are facing a bigger problem in aging society. The population census in 2021 showed that the population over 65 years old in Hong Kong and Macau is 20.2% and 12.2% respectively. Moreover, the elderly care resources in Hong Kong and Macau are relatively scarce, and the cost is generally high. In addition, the elderly population is increasing year by year, therefore the elderly care services in Hong Kong and Macau are under great pressure. With the GBA initiative, GBA is actively exploring ways to encourage elderly from Hong Kong and Macau to move to GBA cities in mainland China. There are increasing numbers of Hong Kong and Macau elderly moving to Dongguan and Zhuhai and nearby cities in recent years. These elderlies found that they can live in a more spacious place and better environment at a lower cost. Especially with the healthcare related GBA Work Plan in place, it is expected that the Hong Kong and Macau elderly will be able to enjoy the same level of medical care as they were at home. Therefore, one can anticipate that more Hong Kong and Macau elderly will be moving to GBA cities in mainland China. Capitals already spotted the opportunity and exploring the possibility to build high standard elderly care institutions to meet this demand.

Guangdong has a lot to learn from The Netherlands in terms of elderly care. The Dutch mature home care model, services and concepts, to name but a few, are appealing illustration. For mid to high-end elderly care institutions, investors are willing to introduce foreign services, concepts and resources to create high standard elderly care institutions to serve people with purchasing power. In addition, mental health for elderly, death education, and hospice care are the areas that Guangdong hopes to improve. Dutch institutions or companies in these areas may find opportunities in Guangdong.

2. Dementia

The needs for dementia care are very different from general elderly care. Care for dementia seniors requires higher professional level and standards. According to the Report on the Status and Development of Nursing Services for the Elderly with Dementia that was published by the China National Committee on Aging in May 2021, the health status of the elderly in China is not optimistic at present. More than 180 million elderly people suffer from chronic diseases, and about 15.07 million elderly over 60 years old suffer from dementia. The number of elderlies with dementia is expected to reach 22.2 million in 2030 and 28.98 million in 2050. The demand for dementia care is growing rapidly, and it is important to have comprehensive preparations in advance before reaching the peak. Guangdong government is starting to pay more attention to dementia. On April 22nd, 2020, Guangdong released a Guideline of Dementia Care in Senior Care Organization. This Guideline specifies the scope, environment requirements, facility and personnel requirements, quality management and many other standards for an institution to provide dementia care to the elderly. The Guideline is only a starting point of dementia care. There are many challenges still ahead. Dutch's dementia care has a good reputation in China market. Technology,

products or services related to dementia care and treatment, physical and mental health for elderly could have market potential. Also, current dementia care in Guangdong is heavily depending on elderly care institutions, there are a lot more elderly with dementia living at home. Home-based dementia care is relatively lacking and could be an opportunity for Dutch companies to tap in. Another challenge the region is facing is about training for dementia care providers. Dutch companies who could help in development of training system, standard and management for dementia care personnel could also see potential in Guangdong.

IV. Conclusion and recommendations

The LSH sector is an important sector for both the Netherlands and China. Guangdong as a province with a highly advanced level of development in various fields within this sector presents various untapped opportunities for collaboration and exchange. The present report outlined that these opportunities are present across the entire value chain: policy exchange, education & skills development, R&D and business. In some fields, such as medicines and medical devices, Dutch companies will need to be selective and focus in advance on the higher end market segments. In other fields such as elderly care, including dementia, opportunities are broader. This report is aimed at providing the Dutch LSH sector with a state of affairs in all these promising fields of both widening and deepening the bilateral cooperation. Dutch companies interested in exploring further the Guangdong market, can rely on the Netherlands Consulate in Guangzhou together with the Embassy in Beijing for relevant market information, assistance in searching for partners and support in (co)organizing events.

Contact Person for LSH Sector in Guangzhou: Ms. Jenesy Wang Senior Commercial Officer Email : Jenesy.Wang@minbuza.nl Embassy of the Kingdom of the Netherlands Mr. Nico Schiettekatte Counselor for Health, Welfare & Sport Email : <u>PEK-VWS@minbuza.nl</u>

For support in other areas of China, please contact the Netherlands Economic Network in China:

Embassy of the Kingdom of the Netherlands:Email: pek-ea@minbuza.nlConsulate-General Shanghai:Email: sha-ea@minbuza.nlConsulate-General in ChongqingEmail: cho-ea@minbuza.nlNBSO Chengdu:Email: nbsochengdu@nbsochengdu.comNBSO Dalian:Email: nbsodalian@nbsodalian.comNBSO Jinan:Email: nbsojinan@nbsojinan.comNBSO Nanjing:Email: nbsonanjing@nbsonanjing.com

V. Annex

A. Listing of major Life Science and Health events in Guangdong

◆ The 7th Guangzhou International Bio-technology Event (BTE)
第 7 届广州国际生物技术大会暨展览会

Date: September 15-17, 2022 Location: Guangzhou, Guangdong

Website: https://www.bteexpo.com/

Brief Introduction: BTE is an annual event hosted in Guangzhou. BTE 2022's topic will focus on the latest progress in cutting-edge technologies such as biological antibodies, immunotherapy, innovative drugs, diagnostic medicine, bio-manufacturing, and vaccine research.

◆ The 8th China International Silver Industry Exhibition (SIC)
第九届中国国际老龄产业博览会

Date: November 18-20, 2022 Location: Guangzhou, Guangdong

Website: http://www.silverindustry.cn/en/

Brief Introduction: this is an annual exhibition focusing in the elderly care industry. The exhibition areas include elderly care services, smart elderly care, rehabilitation and nursing care, health and wellness and barrier-free living. It has been attracting international exhibitors from countries including the U.S., Germany, Denmark, the Netherlands, Canada and etc.

China International Medical Equipment Fair (CMEF)

中国国际医疗器械博览会

Date: October 13-16, 2021 Location: Shenzhen, Guangdong

Website: https://www.cmef.com.cn/en

Brief Introduction: it is a medical equipment show bringing together international medical equipment brands to connect with globally licensed medical equipment distributors, resellers, manufactures, doctors, regulators and government agencies. This exhibition is held twice a year. The spring expo is stationed in Shanghai. The autumn expo rotates in different cities and it often comes to Shenzhen.

✤ The 7th Guangdong Elderly Care Service Summit 第七届广东省养老服务高峰论坛

Date: March 04, 2022Location: Guangzhou, GuangdongWebsite: https://www.sohu.com/a/522625410_100110216

Brief Introduction: this is an annual conference attracts over 5000 participants from healthcare and elderly care industries. Speakers of the conference come from government authorities, public institutions, elderly care service providers, investors and etc.

B. Application Criteria and Procedure for Imported Drugs and Medical Device under GBA Initiative

Application Criteria:

- ✤ Urgently needed for clinical use.
- ✤ With advanced clinical applications.
- Already used in public hospitals of Hong Kong and/or Macau.
- The applicant shall be medical institutions originated from Hong Kong or Macau as wholly owned foreign enterprise, joint venture, or collaboration (technical co-operation or medical consortium) located in the GBA. The institutions shall have medical practice license, and with appropriate professional departments and teams. With adverse event monitoring system and trained people.

Application Procedure:

The application shall be submitted to Guangdong MPA (GDMPA) from medical institutions located in GBA. The qualification evaluation will be jointly performed by GDMPA and Guangdong Health Commission (GD Health Commission). GD Health Commission and GDMPA are responsible to develop a catalogue to specify the allowed devices in the GBA (Catalogue), following consultation with the drug and health administration departments in Hong Kong and Macao. The GBA initiative products will be list-based with dynamic adjustment.

Source: Overview of Regulatory Roadmap for Dutch medical devices products to the Chinese market, published on the RVO website in April 2022.