Accessing Hong Kong-GBA : Essential Information for Overseas Medical Products

June 2025

About us

Cisema

Leading provider of regulatory affairs, quality assurance, clinical research, product testing and safety certification services for **China & Hong Kong**

- Experienced **in-house** and **full-time team** of local, on-the-ground regulatory affairs & quality compliance specialists in our China offices.
- Unlike other consulting firms, we don't simply advise you on what to do or which documents to upload, we actually do it for you, leaving you to focus on your core business.
- Ensure you maintain control of your product registrations and retain unconstrained choice of distributor(s).
- Provide full-cost quotation from the beginning of the project, giving price transparency and clarity for budgeting and planning

20+ years' experience

Sectors:

- Medical devices & IVDs
- Pharmaceuticals
- Cosmetics
- Health foods & supplements
- Industrial goods
- Consumer goods

100 employees worldwide | 12 offices

Hong Kong Market Developments and Regulatory Framework

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Establishment of the Hong Kong CMPR

2024 Progress Highlights:

The Chief Executive's 2023 Policy Address
2023.10.25

- October 31, 2023: ICH Observer
- November 1, 2023: "1+" Mechanism
- June 5, 2024: CMPR Preparatory Office

2025 What to expect:

The Chief Executive's 2024 Policy Address
2024.10.16

- **Early 2025:** Timeline for "Primary Evaluation"
- GBA Clinical Trial Collaboration Platform & Real World Study and Application Centre
- Preparation for statutory regulation for medical devices

Future Developments:

The CMPR aims to adopt a primary evaluation approach, with an expected timeline of eight to ten years to join ICH as a member. Recent international engagements highlight Hong Kong's commitment to becoming a leading health and medical innovation hub.

Hong Kong Health Bureau – Organisation Structure

Lo Chung-mau
Secretary for Health,
Health Bureau

Health Bureau

The Government of the Hong Kong Special Administrative Region
Department of Health

醫院管理局
HOSPITAL AUTHORITY

Drug Office

Medical Device Division

Centre for Medical Products Regulation (CMPR)

Hong Kong Drug Registration

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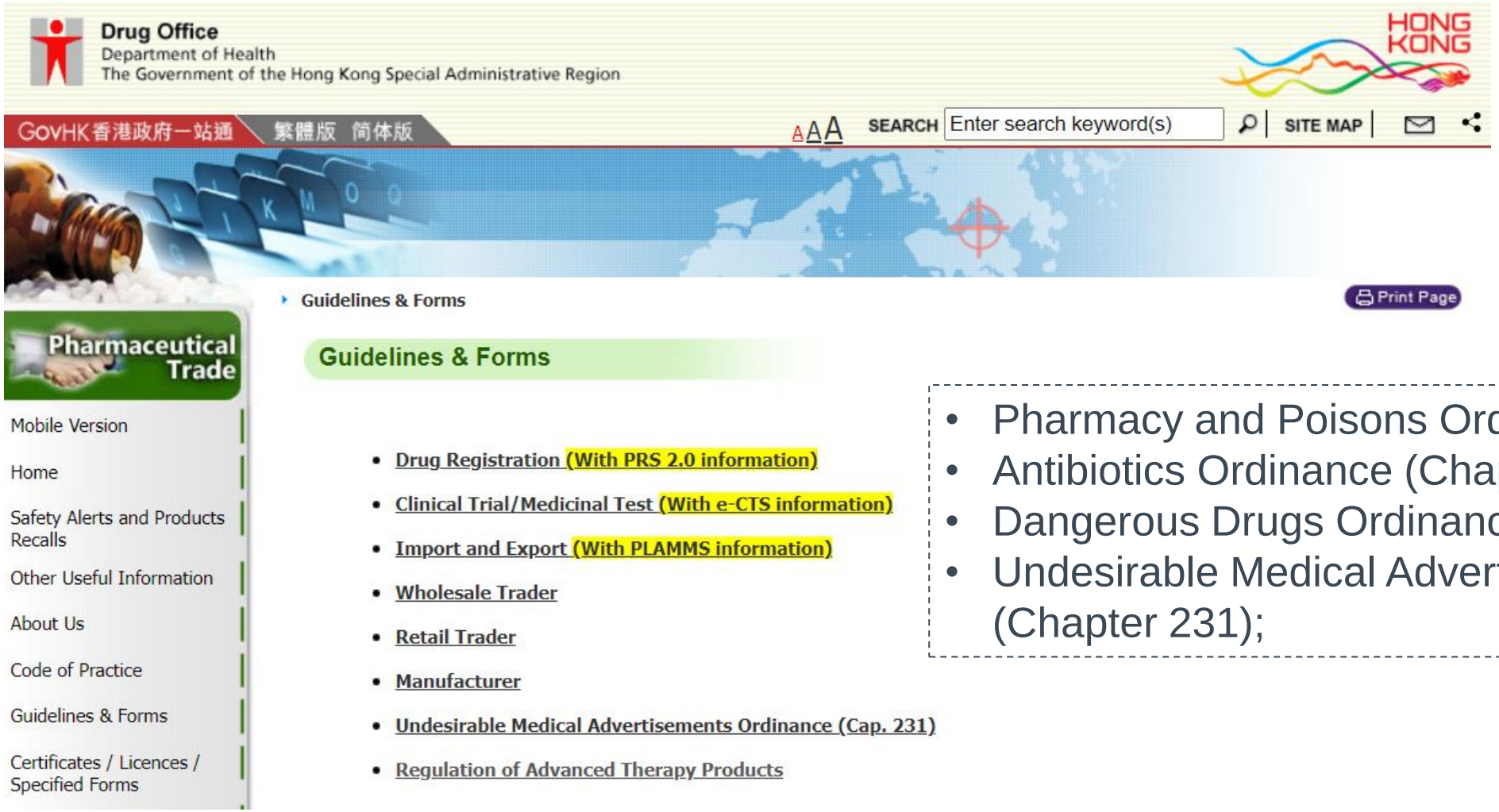
Hong Kong Registration Of Pharmaceutical Products

https://www.drugoffice.gov.hk/



- Pharmacy and Poisons Ordinance (Chapter 138);
- Antibiotics Ordinance (Chapter 137);
- Dangerous Drugs Ordinance (Chapter 134);
- Undesirable Medical Advertisements Ordinance (Chapter 231);

Hong Kong Drug Registration: Dossier

Module 1
– Product Basic Information
– Dose Form, Indication & Pack Size
– Certificate Holder Information (Agent)
– Manufacturer Information (PIC/S GMP Cert.)
– Ingredient Information
– Other Marketing Information (Marketing Approvals issued by other countries / regions)
– Annexed Documents (Electronic copies submission)

Module 2 – Quality Overall Summary (Product)
Module 3 – Quality (Manufacturer)
Module 4 – Non-clinical Study Reports
Module 5 – Clinical Study Reports

Countries recognized by drug office for Free Sale Certificate / Certificate of a Pharmaceutical Product:
Australia, Austria, Belgium, Brazil, Bulgaria, Canada, China, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Holland, Hungary, Ireland, Italy, Japan, Republic of Korea, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, UK and USA

Hong Kong Drug Registration: Procedure & Requirements

1 month +

- Setup account, fill in the application form, and submit the dossier / particulars
- Receive acknowledgement notice from the Hong Kong Drug office

Hong Kong Drug Office's Screening (and may ask for additional documentation)

~11 months for NCE /
~23 months for generics

- Applicant submits the certified true copies (CPPs/FSCs), Modules 2-5, and application fee payment (HKD1100)
- Hong Kong Drug Office asks for additional documents / clarification
- Wait for approval
- Submit the new registration fee payment (HKD1370) and **collect the certificate in person**

Certificate Renewal – Every 5 years (HKD 575)

Change of Registered Particulars (CORP) Application - (HKD155 | 6 months)

Pharmaceutical Products Registered under 1+

Summary by Specialty	Name & Active Ingredient	Indications
Oncology	Elunate Capsules (Fruquintinib)	Metastatic colorectal cancer
	Imdelltra Powder for Concentrate and Solution for Infusion (Tarlatamab)	Small cell lung cancer
	Orpathys Tablets (Savolitinib)	Non-small cell lung cancer with MET exon 14 skipping alterations
Nephrology	Fabhalta Capsules (Iptacopan)	Paroxysmal Nocturnal Hemoglobinuria
	Evrenzo Capsules (Roxadustat)	Anemia in chronic kidney disease
	Orkedia Tablets (Evocalcet)	Parathyroid Disorders

Conditions

- As of November 1, 2023, local unmet medical need of the product for life-threatening or severely-debilitating disease(s). As of November 1, 2024, the "1+" mechanism was extended to cover **ALL NEW DRUGS**.
- Data from local clinical trials or studies showing efficacy to local population.
- Approval from one reference drug regulatory authority.
- Assessment report from local medical experts with at least 5 years of experience in the field of relevance.

Hong Kong Medical Device / IVD Listing

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Hong Kong MD & IVD Listing: Classification

Medical Device Administrative Control System (MDACS) classification rules are closely in line with International Medical Device Regulators Forum (IMDRF)

Product type	Classes				Classification Rules
Medical Devices	I	II	III	IV	16
IVDs	A	B	C	D	7

Increasing risk level

From Voluntary System to Statutory System

The Hong Kong Special Administrative Region
of the People's Republic of China
The Chief Executive's 2024 Policy Address

Reform the Approval Mechanism for Drugs and Medical Devices

94. The Government will expedite the reform of the approval mechanism for drugs and medical devices, including:

(i) extending the "1+" mechanism to all new drugs, including vaccines and advanced therapy products, and improving the approval mechanism to speed up registration, facilitating good drugs for use in Hong Kong;

(ii) devising the timetable for the Hong Kong Centre for Medical Products Regulation and the roadmap towards adoption of "primary evaluation", as well as formulating strategies and measures to facilitate R&D of drugs and medical devices; and

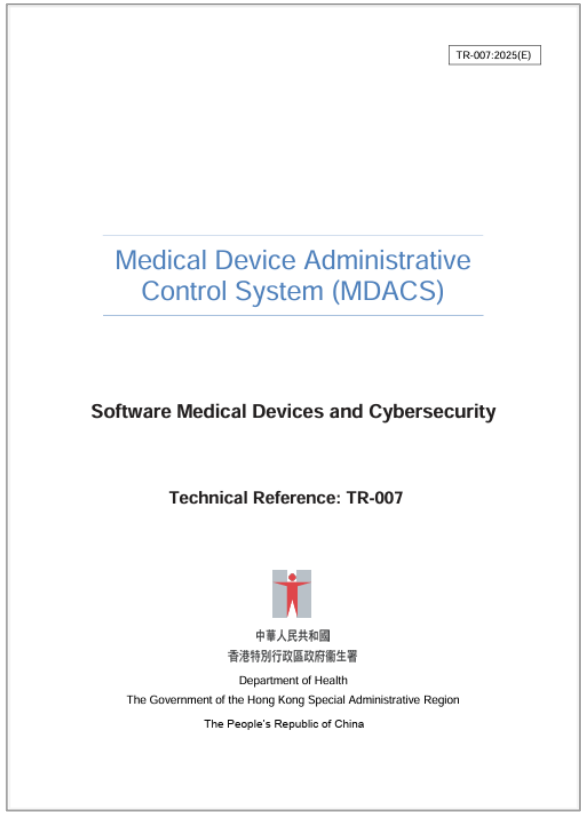
(iii) taking forward preparatory work for legislating for the statutory regulation of medical devices.

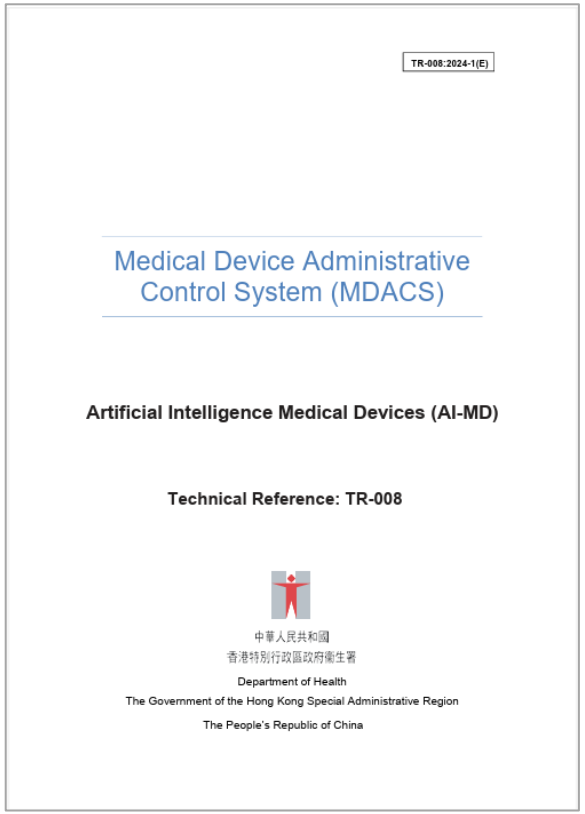
Hong Kong MD & IVD Listing: Documentation

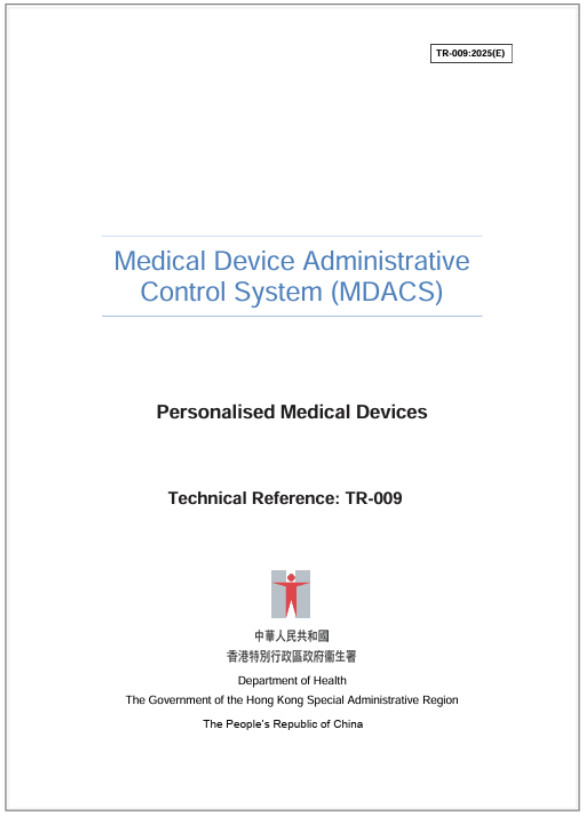
Particulars of Manufacturer	• Manufacturer Information • QMS Certificates
Particulars of Local Responsible Person	• Local Responsible Person Information • Business Registration Certificate • QMS Certificates (if any) • Document Procedures • Designation Letter
Marketing Approvals and Essential Principles	• Foreign Marketing Approvals / Certificates : • Global Harmonization Task Force countries (EU, USA, Canada, Japan, Australia), China, ***Singapore*** ***Newly added in April 2024***, *and South Korea*
Particulars of the Device	• Information about the device and manufacturing site(s) • History of previous recalls and adverse incidents • Instructions for Use (IFU) • Special Listing Information • Labelling and Licensing Requirements • Batch Verification • Conformity Assessment Certificates (if applicable) • Performance Evaluation and Risk Analysis

Latest Technical References

- TR-007 - Software Medical Devices and Cybersecurity
- TR-008 - Artificial Intelligence Medical Devices (AI-MD)
- TR-009 - Personalised Medical Devices







Hong Kong MD & IVD Listing: Milestone Plan

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Collect registration documents
(2 weeks)

- Appoint Local Responsible Person (LRP)
- Submit MDACS application

MDACS Preliminary Check
(~1 month)

- Obtain application number

Supplementary Notice
& provision of additional documents if necessary
(time varies)

- Confirmation of completeness & correctness of dossier submission

MDACS schedule for Board Meeting
(~3 months)

Board Meeting to grant approval & Listing on the MDACS Database

- Class I MDs & Class A IVDs not eligible
- Requires prior market approvals / CAB cert.
- Requires local registered business / LRP
- Minimum appl. processing time: **6 months**
- Application fee: None
- Validity: 5 years

Expedited Approval Scheme

- No reported deaths or serious injury
- No active recalls, field safety corrective actions or adverse events (local & ww)
- Two or more valid, independent regulatory agencies' approval

New Regulations for Hong Kong Public Procurement

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GBA Pathway for Medical Products

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Creation of the Hong Kong/GBA Connect Scheme

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As of March 31, 2025, ***49 drugs*** and ***48 medical devices*** approved

January – July 2021
Pilot Phase

November 2019

- Permitted use of **HK-registered drugs and common MD** in designated HK-owned healthcare institutions in the Greater Bay Area with University of Hong Kong-Shenzhen Hospital to begin with

August 2021

- Guangdong MPA announced the official implementation of "Guangdong Province - Guangdong-Hong Kong-Macao Greater Bay Area Interim Regulations on the Administration of Imported Pharmaceuticals and Medical Devices for Urgent Clinical Needs in China", also known as **GBA connect scheme**

October 2024

- Hong Kong Chief Executive's 2024 Policy Address:
  - **"1+" mechanism**
  - Hong Kong Centre for Medical Products Regulation **(CMPR)**
  - Greater Bay Area International Clinical Trial Institute
  - Real World Study and Application Centre
  - **Statutory Regulation of Medical Devices**

December 1, 2024

- **New Administrative Regulations** for GBA connect scheme

December 26, 2024

- **New Application Guidelines** for GBA connect scheme

44 Designated Institutions

97 Products Approved

<10K Benefited Patients

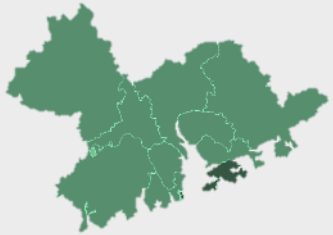
Hong Kong & GBA market size

Population Comparison (2023)

Hong Kong
7.5M

Switzerland
8.8M

UK
68.6M



GBA
86.9M

Healthcare Facilities in Hong Kong

Public Hospitals (HA): 43

Private Hospitals: 13

GBA **Designated Hospitals: 45**

Hong Kong & GBA Regulatory Snapshot (as of April 2025)

14276 Registered Pharmaceuticals

6631 Approved Medical Devices (MDACS) Listings

97 GBA Approvals

GBA Pathway: Pre-Approval Filing

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Applicant fills in the application form

Prepare dossier for submission according to checklist below:	
Proof of purchase and use by public medical institutions in Hong Kong and Macao, as well as approval for sale in the country of origin and other countries. (Applicable to **medical device** only)	Approval documents for sale in Hong Kong or Macao. (Applicable for **pharmaceutical** only)
Samples of packaging, labels, and instructions used in Hong Kong and Macao, along with complete product images.	
Overview of adverse events related to medical devices.	
Summary of clinical use.	
Risk assessment of use. (Applicable to **medical device** only)	
Risk assessment of usage differences among populations.	
Explanation of advanced clinical application.	
Assessment of clinical urgency.	
Academic guidelines/clinical practice guidelines (if applicable).	
Documents related to adverse event monitoring.	
Description of quality management system	
Authorization letter (not required if filled out by overseas holders).	
Commitment letter.	

Guangdong MPA requests for supplementary information

If considered complete

Product information is filed into the Guangdong MPA database

Latest GBA Regulatory Updates

"Regulations on the Administration of Imported Pharmaceuticals and Medical Devices from Hong Kong and Macao to the Nine Mainland Cities of the Guangdong-Hong Kong-Macao Greater Bay Area" *- effective from December 1, 2024, onwards*

Reduced application review time to 10 days for catalogue listed items and 20 days for non-listed items.

Streamlines customs clearance and eliminates port inspections for products urgently needed.

Encourages insurance companies to cover GBA-approved products and improve compensation procedures.

Encourages Real World Studies carried out on GBA approved products for future NMPA registrations:

- PROEM study conducted on Lemborexant for Insomnia (April 12, 2024)
- BEST study conducted on Brolucizumab for Diabetic Macular Edema (June 6, 2024)

(**Source**: Regulations on the Administration of Imported Pharmaceuticals and Medical Devices from Hong Kong and Macao to the Nine Mainland Cities of the Guangdong-Hong Kong-Macao Greater Bay Area)

GBA Pathway: Application Process

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Designated GBA Medical Institution submits application

→ **Provincial Affairs Center** conducts formal review (0-5 days)

Timeline/Process:
35 days → **25 days**
(extra time may incur if dossier is considered in complete)

Is it accepted?

No →
- Incomplete or non-compliant application materials
- unnecessary to obtain administrative approval
- not considered within the jurisdiction of the administrative authority

Yes →

Provincial Evaluation Center conducts technical review (5 days)

→ **Expert evaluation** (15 days → 10 days)

→ Review and joint decision made by the **Provincial MPA and Health Commission** (15 days → 10 days)

→ **Approval documents issued**

→ **Refusal to issue approval documents**

Geographic area & designated hospitals

First Designated GBA medical institution in September 2020

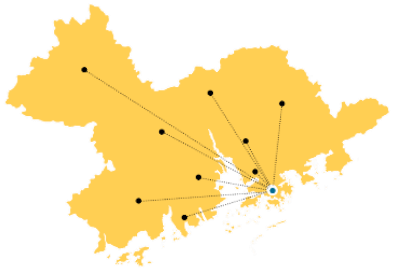
1. Hong Kong University – Shenzhen Hospital

4 Designated GBA medical institutions added in August 2021

2. Modern Hospital Guangzhou
3. Guangzhou United Family Hospital
4. C-MER (Zhuhai) Dennis Lam Eye Hospital
5. Zhongshan Chenxinghai Hospital

Potential future medical institutions:

- 27 Hong Kong-owned healthcare institutions have already been setup in the Greater Bay Area as early as in 2019



14 Designated GBA medical institutions on February 22, 2023

6. The First Affiliated Hospital, Sun Yat-sen University
7. Sun Yat-sen Memorial Hospital, Sun Yat-sen University
8. Nanfang Hospital of Southern Medical University
9. Guangdong Provincial People's Hospital
10. Guangzhou First People’s Hospital
11. Clifford Hospital
12. C-MER (Guangzhou) Dennis Lam Eye Hospital
13. Shenzhen Qianhai Shekou Free Trade Zone Hospital
14. Shenzhen Hyzen Hospital
15. C-MER (Shenzhen) Dennis Lam Eye Hospital
16. The First Affiliated Hospital of Guangzhou Medical University

Hengqin Hospital (former Zhuhai Hengqin Hospital)

17. Foshan Fosun Chancheng Hospital
18. Dongguan Songshan Lake Tungwah Hospital
19. Dongguan Guangming Ophthalmic Hospital

25 New GBA Designated Hospitals

25 Designated GBA medical institutions on September 13, 2024

- First Affiliated Hospital of Sun Yat-sen University (Nansha)
- Third Affiliated Hospital of Sun Yat-sen University
- Sixth Affiliated Hospital of Sun Yat-sen University
- Sun Yat-sen University Zhongshan Ophthalmic Center
- Sun Yat-sen University Cancer Prevention and Treatment Center
- First Affiliated Hospital of Jinan University
- Guangdong Maternal and Child Health Hospital
- Guangdong Provincial Traditional Chinese Medicine Hospital
- First Affiliated Hospital of Guangzhou Medical University
- Guangzhou Medical University Women and Children's Medical Center
- Qianhai Life Guangzhou General Hospital
- Shenzhen Hospital of Southern Medical University
- People's Hospital of Luohu District, Shenzhen
- Maternal and Child Health Hospital of Baoan District, Shenzhen
- Shenzhen New Frontier Health Hospital
- Shenzhen Hengsheng Hospital
- Peking University Shenzhen Hospital
- Fifth Affiliated Hospital of Sun Yat-sen University
- Fosan Qiming Lin Shun Chao Eye Hospital
- Third People's Hospital of Huizhou
- Huizhou Qiming Lin Shun Chao Eye Hospital
- Donghua Hospital in Dongguan
- People's Hospital of Zhongshan City
- Central Hospital of Jiangmen City
- Zhaoqing Zhengda Guo Health Rehabilitation Hospital
- Guangzhou First People's First People's Hospital (updated listing)

Factors for GBA Hospital Procurement

Medical devices & IVDs:

- Products urgently needed for **clinical use**
- Products already procured and operating in public hospitals in Hong Kong or Macao
- Products featuring **advanced technology** in clinical application

Pharmaceuticals:

- Products urgently needed for **clinical use**
- Products already registered in Hong Kong or Macao
- Products not considered to fall under the import permit management as anabolic agents, peptide hormones, etc. in the anesthetic drugs, psychoactive drugs, and stimulants drugs catalogue

Safety | **Efficacy** | **Usage** | **Management System**

Hospital purchase decision is the critical factor

HK-GBA Connect Scheme: Approvals Breakdown

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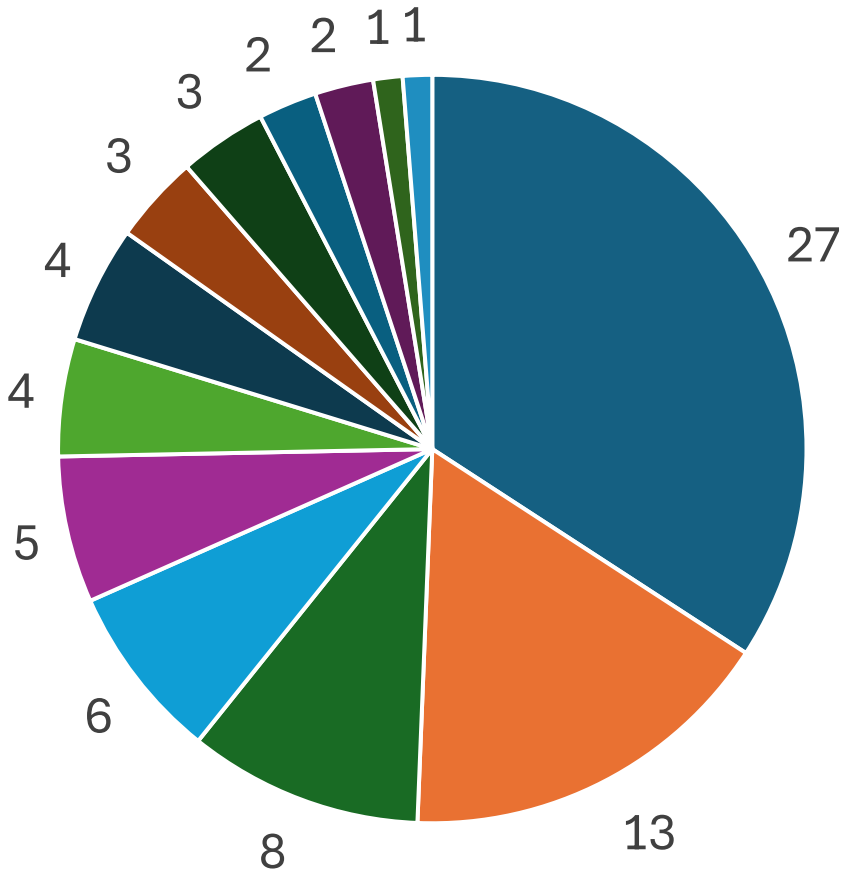
13 Institutions in order of # of Approvals



- HKU-Shenzhen Hospital - 16 drugs & 11 devices
- Sun Yat-sen University Memorial Hospital - 1 drugs & 12 devices
- Foshan Fosun Chancheng Hospital - 3 drugs & 5 devices
- GuangZhou United Family Hospital - 6 drugs
- Guangdong Provincial People's Hospital - 5 devices
- Zhuhai Xima Lin Shun Chao Eye Hopsital - 2 drugs & 2 devices
- The 1st Affiliated Hospital of Sun Yat-Sen Univ. - 2 drugs & 2 devices
- Shenzhen Qianhai Shekou Free Trade Zone Hospital - 3 drugs
- Zhongshan Chen Xinghai Hospital - 3 drugs
- Guangzhou Modern Hospital - 2 drugs
- Guangdong Qifu Hospital - 2 drugs
- Guangzhou First People's Hospital - 1 drugs
- Dongguan Songshan Lake Tungwah Hospital - 1 drugs

GBA Latest Approvals: Pharmaceuticals

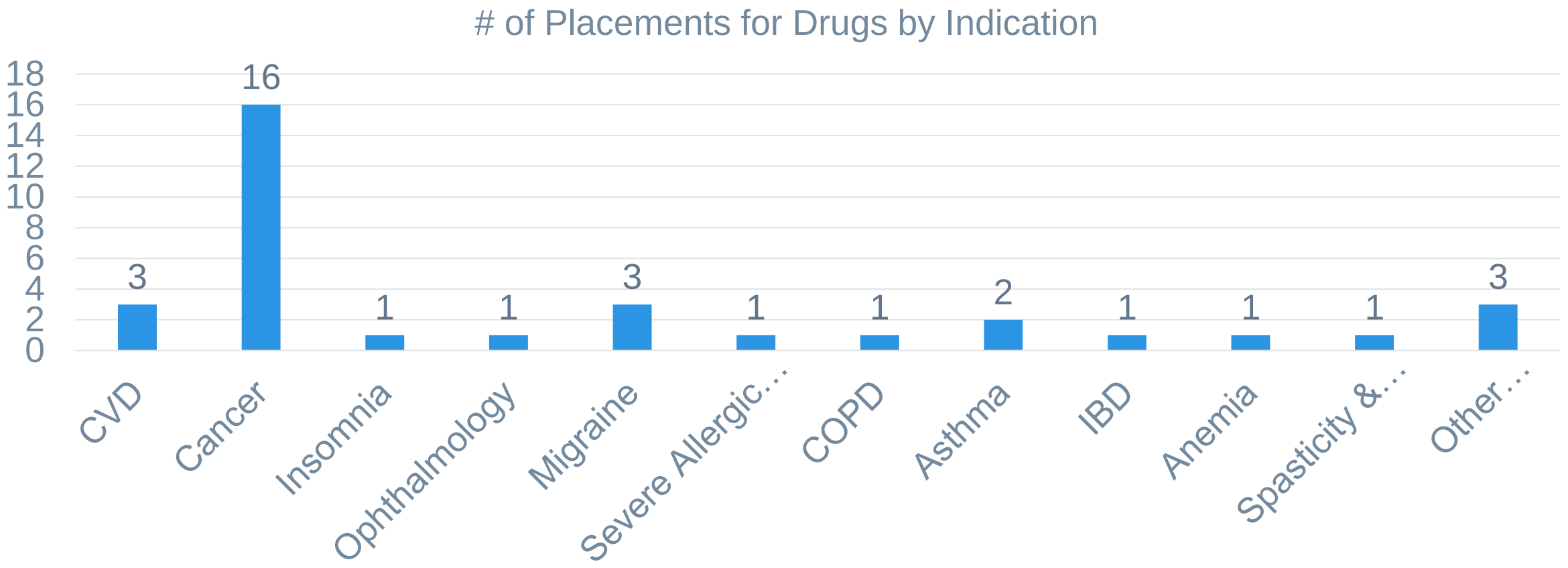
Latest GBA-approved pharmaceuticals:

1. Azacitidine
2. Tremelimumab-actl
3. Lurbinectedin
4. Ropeginterferon alfa-2b
5. Ponatinib
6. Asfotase alfa
7. Anifrolumab
8. Mirvetuximab soravtansine-gynx
9. Ruxolitinib
10. Tezepelumab

NMPA-approved pharmaceuticals following GBA approval:

1. Lorlatinib (Tablets)
2. Entrectinib
3. Polatuzumab Vedotin (Infusion)
4. Inclisiran
5. Erenumab

HK-GBA Connect Scheme: Drug Approval Trends



GBA Latest Approvals: Medical Devices

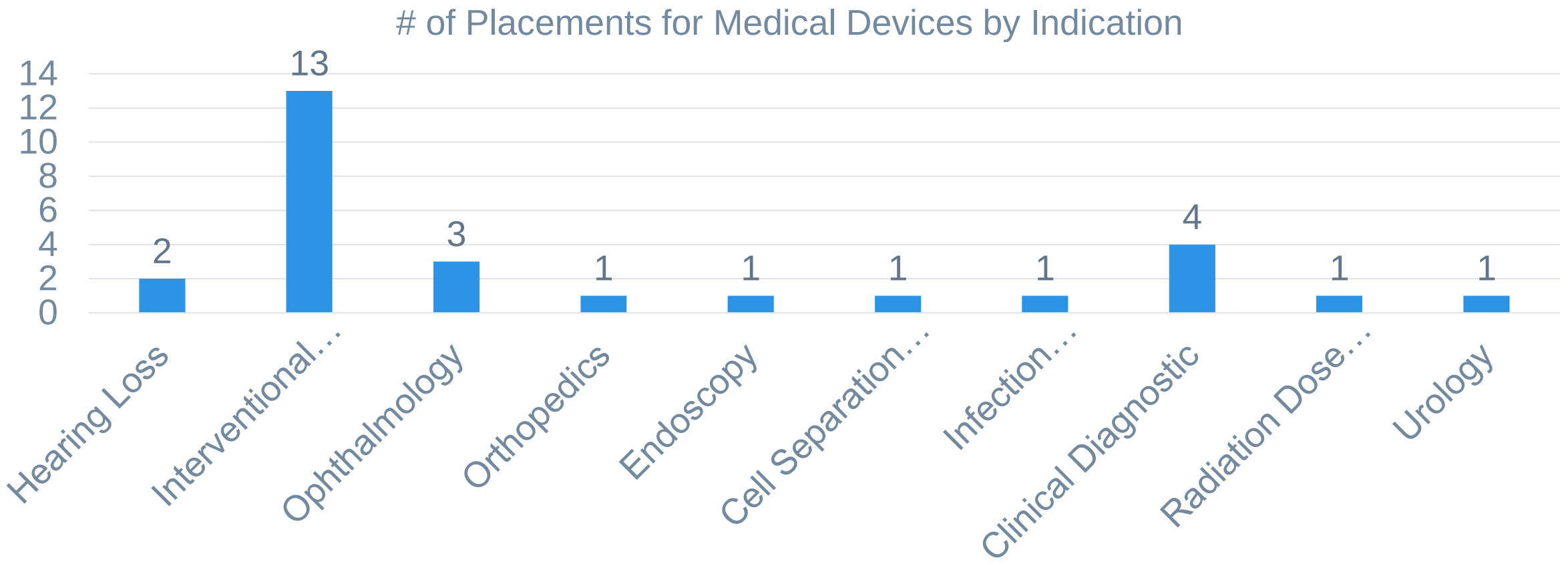
Latest GBA-approved medical devices:

1. Cardiac Resynchronization Therapy Defibrillator
2. Epack
3. Echopulse
4. TriClip G4 Delivery System
5. TriClip Steerable Guide Catheter
6. Aurora EV-ICD MRI SureScan SW041
7. Epsila EV MRI SureScan
8. Epsila EV Sternal Tunneling Tool
9. Epsila EV Transverse Tunneling Tool
10. Aurora EV-ICD MRI SureScan

NMPA-approved medical devices following GBA approval:

1. Anterior segment staining solution
2. SpaceOAR System
3. FARAWAVE Pulsed Field Ablation Catheter
4. FARADRIVE Steerable Sheath
5. FARASTAR Pulsed Field Ablation Generator
6. AveirTM Leadless Pacemaker
7. AveirTM Delivery Catheter
8. AveirTM Introducer
9. AveirTM Retrieval Catheter

HK-GBA Connect Scheme: MD Approval Trends



How Cisema can help

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Cisema Services Overview for HK-GBA

HK MD listing / Drug registration

- Gap analysis between overseas and local market document requirements
- Listing for medical devices under the expedited approval scheme
- Application under the new "1+" mechanism to expedite the approval of new drugs

Filing for GBA Pre-approval

- Manage files prepared according to the dossier review checklist
- Overseas application submission to the Guangdong MPA

Application for GBA pathway

- GBA designated medical institutions investigation for urgent clinical needs
- Facilitate multilateral communication with Guangdong MPA, overseas manufacturers, GBA hospitals, local distributors, etc.

A Possible China Registration Strategy via GBA

A realistic best-case scenario from manufacturer perspective:

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Enabling Compliance in China

Questions?

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