

Result of the tenders of RMB Sovereign Bonds held on June 5, 2024

The following is issued on behalf of the Hong Kong Monetary Authority:

Result of the tenders of RMB Sovereign Bonds held on 5 June 5, 2024:

Tender Result

Tender Date	:	June 5, 2024
Bonds available for Tender	:	2-year RMB Bonds
Issuer	:	The Ministry of Finance of the People's Republic of China
Issue Number	:	BCMKFB24001 (Further Issuance)
Issue and Settlement Date	:	June 7, 2024
Maturity Date	:	March 15, 2026 (or the closest coupon payment date)
Coupon Rate	:	2.20 per cent
Application Amount	:	RMB 8,739 million
Issue Amount	:	RMB 3,000 million
Average Accepted Price	:	100.18
Lowest Accepted Price	:	100.09
Highest Accepted Price	:	100.69
Allocation Ratio (At Lowest Accepted Price)	:	Approximately 17.45 per cent

Tender Result

Tender Date	:	June 5, 2024
Bonds available for Tender	:	3-year RMB Bonds
Issuer	:	The Ministry of Finance of the People's Republic of China
Issue Number	:	BCMKFB24002 (Further Issuance)
Issue and Settlement Date	:	June 7, 2024
Maturity Date	:	March 15, 2027 (or the closest coupon payment date)
Coupon Rate	:	2.28 per cent
Application Amount	:	RMB 9,624 million
Issue Amount	:	RMB 3,000 million
Average Accepted Price	:	100.41
Lowest Accepted Price	:	100.26

Highest Accepted Price : 101.15
Allocation Ratio (At Lowest Accepted Price) : Approximately 65.00 per cent

Tender Result

Tender Date : June 5, 2024
Bonds available for Tender : 5-year RMB Bonds
Issuer : The Ministry of Finance of the People's Republic of China
Issue Number : BCMKFB24003 (Further Issuance)
Issue and Settlement Date : June 7, 2024
Maturity Date : March 15, 2029 (or the closest coupon payment date)
Coupon Rate : 2.39 per cent
Application Amount : RMB 8,908 million
Issue Amount : RMB 3,000 million
Average Accepted Price : 100.69
Lowest Accepted Price : 100.41
Highest Accepted Price : 102.22
Allocation Ratio (At Lowest Accepted Price) : Approximately 37.96 per cent

Tender Result

Tender Date : June 5, 2024
Bonds available for Tender : 10-year RMB Bonds
Issuer : The Ministry of Finance of the People's Republic of China
Issue Number : BCMKFB24004 (Further Issuance)
Issue and Settlement Date : June 7, 2024
Maturity Date : March 15, 2034 (or the closest coupon payment date)
Coupon Rate : 2.45 per cent
Application Amount : RMB 5,466 million
Issue Amount : RMB 2,000 million
Average Accepted Price : 100.88
Lowest Accepted Price : 100.00
Highest Accepted Price : 104.88
Allocation Ratio (At Lowest Accepted Price) : Approximately 6.99 per cent

LCQ20: Tenancy control on subdivided units

Following is a question by Dr Hon Wendy Hong and a written reply by the Secretary for Housing, Ms Winnie Ho, in the Legislative Council today (June 5):

Question:

Part IVA of the Landlord and Tenant (Consolidation) Ordinance (Cap. 7) (the Ordinance), which seeks to implement tenancy control on subdivided units (SDUs), came into force on January 22, 2022. Under the Ordinance, a landlord is required to submit a Notice of Tenancy (i.e. Form AR2) to the Rating and Valuation Department (RVD) within 60 days after the commencement of the tenancy term to account for the contents of the tenancy agreement. However, there are views that while the Ordinance has been in force for more than two years, RVD has only processed about 30 000 Forms AR2 among some 110 000 SDUs across the territory, indicating that a large number of landlords have yet to fulfil their legal obligations. Moreover, since 2023, RVD has also provided Form AR3 and Form AR4 to facilitate the relevant SDU tenants to enquire with RVD about the submission of Forms AR2 by their landlords, and to report their landlords' acts of suspected offences. In this connection, will the Government inform this Council:

- (1) of the respective numbers of Forms AR3 and Forms AR4 received to date;
- (2) given that as at the end of March this year, RVD has processed a total of 29 354 Forms AR2, and among them, of the number of those which were only returned upon RVD's following up on the relevant Forms AR3 and Forms AR4;
- (3) of the number of SDUs reported by Form AR2 to date, together with a breakdown by type (i.e. room, cubicle, rooftop house, podium house, loft, bedspace, space capsule and other type) and their respective percentages;
- (4) as the Bedspace Apartments Ordinance (Cap. 447) applies to flats in which there are 12 or more single bedspaces for rent, whether it applies to flats in which 12 or more SDUs of types referred to in Form AR2, such as cubicles or bedspaces, are provided; how the authorities regulate the building structure, fire safety and environmental hygiene of flats in which less than 12 such cubicles or bedspaces are provided;
- (5) given that as at the end of February this year, RVD has received a total of 635 tenancy complaints about SDUs, following an increase in the number of successful prosecutions instituted by RVD against unlawful landlords over the past two years, whether there has been a corresponding decrease in the number of relevant complaints; if so, of the details; and

(6) given that while the Government set up the Task Force on Tackling the Issue of SDUs last year, which was committed to eradicating substandard SDUs, there are views that as SDUs' facilities are upgraded, the rents of such units will go up, thus adding to the burden on tenants, and that grass-roots tenants of bedspaces and cubicles will be the first to bear the brunt of such a rental increase, whether RVD has conducted assessment in this regard; if so, of the details; if not, the reasons for that?

Reply:

President,

The Government of the Hong Kong Special Administrative Region has all along been paying attention to the housing needs of those who are inadequately housed, and proactively taking different measures with a view to improving the living environment of relevant households.

The Government has been striving to identify land for housing development to increase the overall supply of public and private housing. There has been sufficient land identified to meet the public housing demand of 308 000 units in the coming 10 years, thereby catering for the housing needs of the grassroots. Moreover, tenancy control on subdivided units (SDUs) has been implemented since January 2022, providing protection to tenants in various aspects which include four-year security of tenure; restricting the rate of rent increase on tenancy renewal with a cap of 10 percent; prohibiting landlords from overcharging tenants on utilities and services, etc. Besides, the 2023 Policy Address announced the establishment of the Task Force on Tackling the Issue of SDUs for conducting an in-depth study on the comprehensive handling of the SDU issue, and the Task Force will provide detailed recommendations to the Chief Executive in August this year.

Having consulted the Rating and Valuation Department (RVD) and the Home Affairs Department (HAD), the reply to various parts of the question raised by Dr Hon Wendy Hong is as follows:

(1) to (3) and (5) Pursuant to Part IVA of the Landlord and Tenant (Consolidation) Ordinance (Cap. 7) (the Ordinance) which implements SDU tenancy control, the landlord must, within 60 days after the term of the regulated tenancy commences, submit a Notice of Tenancy (Form AR2) to notify RVD of the particulars of the tenancy. To allow more tenants to benefit from tenancy control, the definition of SDU under the Ordinance is relatively broad, i.e. premises that form part of a unit of a building, thereby covering rooms, cubicles, rooftop houses, podium houses, lofts, bedspaces, space capsules, etc. A landlord who refuses or neglects to comply with the above requirement on submission of Form AR2 without reasonable excuse commits an offence and is liable to a maximum fine at level 3 (\$10,000), and in the case of a continuing offence, to a further fine of \$200 for each day during which the offence continues.

As at mid-May 2024, RVD processed a total of 31 764 Forms AR2. After

excluding those Forms AR2 with tenancies not meeting the definition of regulated tenancy under the Ordinance and thus not required to be submitted to the Commissioner of Rating and Valuation, there were 26 964 valid Forms AR2. Among them, 26 350 (i.e. 97.7 percent) were SDUs under the category of "room" and the remaining 614 (i.e. 2.3 percent) were SDUs under other categories (i.e. cubicle, rooftop house, podium house, loft, bedspace, space capsule, etc.).

RVD has further provided two types of forms (i.e. Forms AR3 and AR4) since April and October 2023 respectively to facilitate tenants of regulated tenancies to enquire whether RVD has received the relevant Form AR2 and to report to RVD the landlords' acts of suspected offence(s) (including contravention of the requirement on the submission of Form AR2). As at end-April 2024, the total number of Forms AR3 and AR4 received by RVD was 98. Apart from Forms AR3 and AR4, the tenants concerned may continue to enquire or report to RVD through telephone hotline, email, fax, post, or visiting the office of the Tenancy Services Section of RVD in person. As at end-April 2024, RVD received a total of 678 complaints relating to SDU tenancy control (including complaints made through Forms AR3 and AR4), and there was no obvious trend in the relevant complaint figures.

Since the Ordinance came into force, RVD has been encouraging landlords through publicity and education to abide by the law, and has been taking resolute enforcement actions to combat illegal acts. As at end-April 2024, RVD identified a total of 3 226 cases of landlords suspected of contravening the Ordinance, amongst which 2 991 were proactively identified by RVD through different channels and the remaining 235 were complaint cases. According to the latest prosecution figures as at end-May 2024, RVD successfully prosecuted 269 cases involving a total of 231 SDU landlords, with fines amounting to a total of \$492,010. Apart from the prosecution cases, RVD also issued warning letters to the landlords of 1 435 cases relating to Form AR2 after consulting the Department of Justice. To further step up the efforts in combating illegal acts, apart from the current enforcement and prosecution work that handles an average of around 1 400 suspected offence cases each year, RVD has separately set a key performance indicator on top of the current 1 400 caseloads, targeting to proactively check an extra of no less than 1 000 landlords of SDU households in 2024-25 on whether they have committed offences for regulated tenancies. The aforesaid annual caseload of handling some 1 400 suspected offence cases as well as the proactive checking of an extra of no less than 1 000 landlords of SDU households have demonstrated RVD's determination in combating illegal acts through redoubled enforcement efforts. RVD has already started issuing letters to the landlords of targeted SDU households by batches to require them to provide tenancy-related information to RVD for checking.

RVD will continue to identify cases of suspected contravention of the Ordinance through suitable channels and means, and promote the Ordinance as well as the relevant statutory requirements. Based on more than two years' experience of implementing the Ordinance, the number of Form AR2 received by RVD in 2023 increased by 36 percent as compared with 2022, and the number of Form AR2 received in 2024 has thus far sustained the increasing trend. We

expect that the continuously strengthened enforcement and publicity efforts should help sustain the aforesaid increasing trend regarding the number of Form AR2, which would hopefully result in the total number of Form AR2 received reaching more than 40 000 by end-2024.

(4) The purpose of the Bedspace Apartments Ordinance (Cap. 477) (BAO) is to ascertain that the flats intended to be used as bedspace apartments comply with relevant building and fire safety requirements. Pursuant to BAO, any flats with 12 or more bedspaces intended to be used as sleeping accommodation for individuals under rental agreements must obtain a licence before commencing operation. The Office of the Licensing Authority (OLA) under HAD is responsible for issuing licences and enforcement under BAO. For any flats that are not regulated by BAO, they are subject to the regulations related to building, hygiene and fire safety as stipulated in the Buildings Ordinance (Cap. 123) and the Fire Services Ordinance (Cap. 95). If OLA is aware of or discovers any premises not being regulated under BAO but are suspected of violating other relevant legislation, OLA will refer the cases to relevant departments for follow-up.

(6) Since the establishment of the Task Force on Tackling the Issue of SDUs in October 2023, relevant policy bureaux and departments have conducted multiple rounds of internal discussion on the issues of setting minimum standards of living conditions for SDUs, eradicating substandard SDUs, etc. We have also commissioned a consultant to visit different types of SDU households across Hong Kong to collect the relevant data so as to assist the Task Force in understanding the latest situation of existing SDUs and relevant households. At the same time, the Task Force has been gauging the views of different stakeholders, with a view to formulating a feasible and pragmatic solution that can tackle the SDU issue in an orderly manner.

The issue of SDUs is complicated and involves the wellbeing of tens of thousands of families. Therefore, eradicating substandard SDUs is not a short-term target which can be achieved overnight. When formulating the relevant policies, the Task Force will require that all SDUs being operated/rented out should provide reasonable and safe living environment, and at the same time, there should not be SDU households being rendered homeless as a result of the eradication actions. The Task Force will also carefully balance the impacts of the relevant policies on the SDU rental market (including rental level) as well as the tenants.

It is worth noting that the prevailing SDU tenancy control has implemented certain regulation on the rent of SDU tenancies, i.e. the rate of rent increase on tenancy renewal between the first term tenancy and second term tenancy must not exceed the percentage change of the territory-wide rental index of private domestic properties during the relevant period, and is capped at 10 percent. Besides, RVD has published the SDU rental information collected via Form AR2 on its website on a monthly basis since May 2023, allowing landlords and tenants to make reference to relevant market information when determining the rent. In addition, the Government has identified sufficient land to meet the public housing demand of 308 000 units in the coming 10 years. Coupled with the short-term supply of about 21 000

Transitional Housing units and about 30 000 Light Public Housing units in the next few years, the housing needs of those inadequately housed (including SDU households) should be better catered for and the demand for SDUs from the grassroots is expected to reduce gradually.

LCQ9: Promoting development of stablecoins and virtual assets

Following is a question by the Hon Yim Kong and a written reply by the Acting Secretary for Financial Services and the Treasury, Mr Joseph Chan, in the Legislative Council today (June 5):

Question:

There are views that promoting the development of stablecoins and virtual assets (VAs) in Hong Kong will help the Government enhance its initiative of disbursing electronic consumption vouchers to inbound tourists and leverage advanced technologies to drive the development of the local real economy, and that the Government can also take the opportunity to vigorously develop the technologies and industries related to Web 3.0, blockchain, stablecoins and VAs to strengthen Hong Kong's status as an international financial centre in the long run. In this connection, will the Government inform this Council:

(1) given that the Government has introduced measures to provide concessions for inbound tourists, such as the distribution of night market consumption discount vouchers, whether the Government will consider carrying out the relevant work in an electronic and digital manner through related technologies such as blockchain and VAs, so as to enable tourists to obtain and use the consumption vouchers more conveniently at scenic spots, restaurants, hotels or other retail premises, and at the same time effectively reduce the costs of disbursing and managing the consumption vouchers;

(2) whether the Government will collaborate with the relevant industries to launch a platform powered by stablecoin and VA technologies for the disbursement and use of consumption vouchers; if so, of the specific plan; if not, the reasons for that; and

(3) as there are views that Hong Kong has a large pool of talents in finance, Web 3.0 industry and Internet, as well as a regulated financial services industry and a flexible market mechanism that bridges markets in the East and the West, whether the Government will consider leveraging the relevant advantages to further promote innovation and development of virtual and digital currency transactions, so as to strengthen Hong Kong's position as an

international financial centre, thereby contributing to the digitisation and internationalisation of Renminbi for the country?

Reply:

President,

In consultation with the Tourism Commission, the Hong Kong Monetary Authority (HKMA), and the Securities and Futures Commission (SFC), the reply to the question raised by Hon Yim is as follows:

(1) and (2) The Hong Kong Tourism Board (HKTB) has been providing visitors with spending offers through its one-stop web-based e-platform with the aim of making the offers more convenient for visitors and enhancing their efficiencies. For instance, the HKTB handed out about two million sets of "Hong Kong Goodies" visitor consumption vouchers via the one-stop web-based e-platform since February 2023. Visitors could enjoy a welcome drink in one of the participating bars, restaurants or hotels, or redeem their vouchers for an offer in one of the 3 800 participating outlets of attractions, public transport, dining and retail outlets.

Moreover, in support of the Government's call for boosting night-time ambience, the HKTB also handed out one million sets of "Hong Kong Night Treats" visitor consumption vouchers through the one-stop web-based e-platform starting from November 2023. Each voucher offered visitors a HK\$100 discount on night-time dine-in experience in town to encourage visitors to enjoy Hong Kong's night-time gastronomic experiences.

(3) In view of the rapid development of the virtual asset (VA) market, putting in place a robust and transparent regulatory environment capable of adapting to the evolving landscape is of foremost importance to facilitating Web3 development and financial innovation. In this regard, the Government and regulators have been upholding the "same activity, same risks, same regulation" principle in taking forward the orderly development of the VA industry, with suitable measures introduced in the process to mitigate the risks involved in VA activities and protect investors' interest. This policy direction has been clearly set out in our Policy Statement on Development of Virtual Assets in Hong Kong issued in October 2022. A suitable regulation of VA services can facilitate responsible and healthy market development, and protect investor's interests.

With the Legislative Council's (LegCo) passage of the Anti-Money Laundering and Counter-Terrorist Financing (Amendment) Bill 2022 in December 2022, the SFC-administered VA service provider licensing regime commenced operation in June 2023. Currently, there are two licensed platforms providing bitcoin and ethereum trading services to retail investors. The development of VA-related products has been progressing in an orderly and positive manner in Hong Kong. Following the listing of three VA futures exchange-traded funds (ETFs) in Hong Kong in early 2023, the SFC issued a circular in December 2023 to start receiving applications for VA spot ETFs. Within just a few months, the first batch of six VA spot ETFs issued by three fund companies were

listed in Hong Kong, as the forerunner in Asia.

Looking forward, we in co-ordination with the financial regulators will endeavour to continue to enhance the regulatory framework, including introducing licensing regimes for fiat-referenced stablecoin issuers and VA over-the-counter service providers. We have completed public consultations on the proposals, and will introduce relevant Bills into LegCo as soon as possible. The HKMA has also launched the stablecoin issuer "sandbox" to allow institutions planning to issue stablecoins in Hong Kong to conduct testing on their operational plans in a risk-controlled environment and facilitate two-way communications on the proposed regulatory requirements, so as to ensure that the design of the regime will attain the regulatory objective.

Besides, we have been working closely with the financial regulators and industry stakeholders to promote the development of Fintech through multi-pronged measures, including enhancing the financial infrastructure, building a more active Fintech ecosystem, nurturing Fintech talents, as well as strengthening the connection and co-operation with Mainland and overseas parties, thereby solidifying Hong Kong's status as an international financial centre while contributing to the digitisation and internationalisation of Renminbi. In May 2024, the HKMA announced that it would expand the scope of e-CNY pilot in Hong Kong with the People's Bank of China (PBoC). This would facilitate the set-up and use of e-CNY wallets by Hong Kong residents, as well as the top-up of e-CNY wallets through the Faster Payment System, thereby further facilitating cross-boundary retail payments of the residents in both places. In addition, the HKMA will continue to work with the Digital Currency Institute of the PBoC to explore allowing Hong Kong residents to upgrade their e-CNY wallets to higher tiers through real-name verification, as well as enhancing the interoperability in payments to provide more convenient payment experience for users (including individuals and merchants). The central banks in both places will also explore corporate use cases, with a view to facilitating cross-boundary trade settlement.

[LCQ4: Support for retail enterprises](#)

Following is a question by the Hon Adrian Ho and a reply by the Secretary for Commerce and Economic Development, Mr Algernon Yau, in the Legislative Council today (June 5):

Question:

There are views pointing out that the recent changes in the consumption habits of members of the public and the consumption patterns of inbound tourists have posed a great challenge to the retail industry in Hong Kong, and a number of shopping malls have experienced winding-up of businesses and surrender of tenancies. In this connection, will the Government inform this

Council:

(1) whether it has plans to introduce measures such as rent concessions for tenants operating in its properties (including public markets and cooked food centres) and to discuss with operators of private shopping malls the provision of lease incentives for existing tenants to renew their tenancies and attracting new tenants, so as to help increase the occupancy rate and tenancy renewal rate, thereby maintaining a favourable retail market situation;

(2) as it is learnt that the revitalised Central Market has operated well, attracting more than 26 million visitors in two years while providing business space for street snack vendors, local brands and small shops with unique characteristics, etc, whether the authorities have plans to draw on the relevant experience and use public markets or shopping malls with fewer visitors and vacant stalls/shops as pilot projects for revitalisation, coupled with effective promotional efforts to attract patronage by members of the public and tourists from the Mainland and overseas; if so, of the details; if not, the reasons for that; and

(3) of the current plans of the relevant government departments to provide support to Hong Kong's small and medium retailers to help them tide over the current retail downturn, and to extend the level of support provided by the Anti-epidemic Fund to small and medium enterprises during the epidemic?

Reply:

President,

Hong Kong's economy has been recovering steadily in the past year. In the first quarter of this year, the real gross domestic product grew by 2.7 per cent over the preceding year, marking the fifth consecutive quarter of growth. Some recent data show that the economic performance remains positive in general, including the increase in the number of inbound visitors and the continuous improvement in the exports of goods. The forecast of economic growth for 2024 is maintained at 2.5 per cent to 3.5 per cent.

As for the total retail sales, the data of the Census and Statistics Department reflect that there was an increase of 16.2 per cent in 2023 as compared with 2022, from around \$350 billion to around \$407 billion.

Along with rise in employment earnings, the recent stabilisation of asset markets and the further revival in inbound tourism with the number of visitors expected to increase by 35 per cent to 46 million in 2024 as compared with that in 2023, coupled with the Government's continued efforts in promoting mega event economy and stimulating consumption sentiment, and the Central Government's further enhancement to the Individual Visit Scheme by extending its scope from 49 to 59 cities to cover all provincial capitals in the country, the local retail sector is expected to benefit directly.

Having consulted the Environment and Ecology Bureau and the Innovation,

Technology and Industry Bureau, the consolidated reply to the three parts of the question is as follows:

The Government does not compile statistics on the leasing situation of private shops. According to the latest data released by a real estate services organisation, the street shop vacancy rate has improved from 18.3 per cent in the third quarter of 2020 (the highest level during the epidemic) to 6.6 per cent in the first quarter of 2024. The vacancy rate in some of the core districts (such as Causeway Bay and Tsim Sha Tsui) was even lower than 6.6 per cent.

Government properties are managed by different policy bureaux and departments, and are rented out in accordance with the relevant policies (such as through open rental bids). For public markets and cooked food centres, being part of government properties, the Government currently does not have any plan to introduce rental concession measure.

As regards the leasing situation of shops in the private market, the Government is of the view that it should be market-driven, allowing private organisations to make adjustments having regard to factors such as the business operating environment, market conditions, location and vacancy rate of shops, etc.

In recent years, the consumption pattern of residents and inbound visitors keeps on changing, posing challenges to small and medium enterprises (SMEs) in the retail sector. The Government has been providing assistance to SMEs (including those in the retail sector) having regard to the economic situation and the needs of the trade, with a view to helping them cope with liquidity shortage, and encouraging them to enhance their competitiveness and develop more diversified markets.

To assist enterprises hard hit by the epidemic in coping with cash flow problems, the Government launched in April 2020 the Special 100% Guarantee Product under the SME Financing Guarantee Scheme (SFGS) to provide low-interest concessionary loans to SMEs. As at end March 2024, a total of nearly \$19 billion of loans has been approved under the SFGS for SMEs in the retail sector, benefitting over 6 000 enterprises and nearly 53 000 employees. In view of the ongoing challenges faced by SMEs, the Government extends in this year's Budget the application period for the 80% and 90% Guarantee Products under the SFGS for two years to end March 2026, so as to assist more SMEs (including those in the retail sector) in coping with cash flow problems.

At the same time, the Government has also been actively supporting SMEs to carry out promotion activities and develop their businesses. Among others, the SME Export Marketing Fund (EMF) provides funding support for SMEs to participate in export promotion activities to expand their markets outside Hong Kong. The funding scope has been expanded following the implementation of the special measure from April 30, 2021, to June 30, 2026, to cover large-scale exhibitions and online exhibitions targeting the local market. As at end April 2024, the EMF has approved more than 31 400 applications from the wholesale and retail sector, benefitting over 6 800 enterprises and involving

a total funding of \$700 million.

In addition, the Government has allocated funding to launch the Digital Transformation Support Pilot Programme, under which subsidies will be provided on a one-to-one matching basis to assist SMEs in retail and food and beverage industries in applying e-payment and other ready-to-use basic digital solutions, so as to expedite their digital transformation.

The above-mentioned measures should help alleviate the operating pressure on the retail sector and help the sector further develop businesses. As Hong Kong's economy is recovering and the number of inbound visitors is increasing, the local retail sector will be given a greater impetus of recovery. The Government will continue to closely monitor the situation, and assist SMEs in riding out the storm having regard to the situation.

DH establishes Preparatory Office for Hong Kong Centre for Medical Products Regulation

â€‹The Department of Health (DH) announced today (June 5) the establishment of the Preparatory Office for the Hong Kong Centre for Medical Products Regulation (CMPR) to put forward proposals and steps for the formal establishment of the CMPR, and to study the potential restructuring and strengthening of the regulatory and approval regimes for drugs and medical devices.

The Chief Executive's 2023 Policy Address (Policy Address) announced that the Government will leverage the medical strengths of the Hong Kong Special Administrative Region (HKSAR) with the long-term objective of establishing an authority that registers drugs and medical devices (medical products) under the "primary evaluation" approach, i.e. to directly approve applications for registration of medical products in Hong Kong based on clinical trial data, without relying on registration approval from other drug regulatory authorities. This will help accelerate the clinical use of new drugs and medical devices, and foster the development of industries relating to the research and development (R&D) and clinical trials of medical products, developing Hong Kong into an international health and medical innovation hub.

Hong Kong would become an internationally renowned regulatory authority and implement the "primary evaluation" approach for medical products in six major steps (see Annex). In more than six months following the announcement of the Policy Address, the HKSAR Government has implemented measures in all respects and achieved results.

Firstly, with the support and guidance of the National Medical Products Administration (NMPA), Hong Kong, China has officially become an observer of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (Note 1) on October 31, 2023. This allows Hong Kong to familiarise itself with the latest developments in the drug regulation regime, to further align Hong Kong with the World Health Organization (WHO)-Listed Authority.

Secondly, the HKSAR Government implemented a new mechanism for the approval of new drugs (the "1+" mechanism) on November 1, 2023. Under the "1+" mechanism, holders of registration from one of the recognised drug regulatory authorities (instead of two) for drugs containing new chemical or biological entities could apply for registration in Hong Kong, on the condition that they could provide local clinical data that complies with the requirements and information recognised by local experts. Since the implementation of the "1+" mechanism, the DH has received more than 210 inquiries from about 70 pharmaceutical companies, including many pharmaceutical companies from overseas and the Mainland. Under the "1+" mechanism, two new drugs for cancer treatment have already been approved for registration, bringing new hopes of treatment to patients.

Considering the establishment of the Preparatory Office for the CMPR under the DH today, the HKSAR Government has completed the first three of six major steps. The specific work of the Preparatory Office includes:

(i) comprehensively studying and planning a regulatory and approval regime for drugs and medical devices suitable for Hong Kong;

(ii) putting forward proposals and steps for the establishment of the CMPR;

(iii) conducting a review on the need for amending existing legislation to promote the development of medical products regulation; and

(iv) making recommendations to the Steering Committee on Health and Medical Innovation and Development (Note 2) as well as maintaining close communication with various stakeholders.

The HKSAR Government will continue to actively follow up on the remaining major steps, including the establishment of the CMPR and the implementation of the "primary evaluation" approach for medical products. Based on international experience, it usually takes about eight to 10 years from initial engagement with the ICH to becoming an ICH regulatory member.

In May this year, the Commissioner of the NMPA led a delegation to visit Hong Kong and signed the Co-operation Agreement on Regulation of Drugs with the Health Bureau of the HKSAR Government. The Agreement underpinned the liaison and co-ordination arrangements among the NMPA, the DH, and the CMPR to be set up. In the same month, the Secretary for Health, Professor Lo Chung-mau, along with the Director of Health, Dr Ronald Lam Man-kin, led a Hong Kong, China delegation to attend the 77th World Health Assembly held in Geneva, Switzerland, as members of the Chinese delegation. They had then

visited multinational pharmaceutical and healthcare enterprises, and a clinical trial centre. During the visit, they highlighted Hong Kong's unique advantages and the latest developments in health and medical innovation to various WHO and other government officials and organisations responsible for healthcare, as well as international scientific research and medical experts (including the Director for Regulation and Prequalification of the WHO and personnel from the Clinical Trials Center of the University Hospital Zurich). Multinational pharmaceutical and healthcare enterprises which were visited welcomed the HKSAR Government's plan to establish the CMPR and the initiatives to develop a health and medical innovation hub.

The HKSAR Government will continue to attract more pharmaceutical and medical device enterprises, both locally and from around the world, to conduct R&D and clinical trials in Hong Kong, and build the capacity, recognition and status to ensure that the eventual approval mechanism of medical products in Hong Kong would be widely recognised internationally and by the Mainland, and develop Hong Kong into an international health and medical innovation hub.

Note 1: The ICH is an international recognised association. The mission of the ICH is to harmonise the technical requirements for drug registration among its members and to promulgate various guidelines on safety, efficacy and quality that are recognised as the highest global standards for the protection of public health.

Note 2: The Steering Committee on Health and Medical Innovation and Development (SCHMID) is chaired by the Secretary for Health and comprises members from the Innovation, Technology and Industry Bureau, relevant bureaux, departments, institutions, and local medical schools. SCHMID is tasked with co-ordinating and advancing the work related to health and medical innovation, and advising the Government on the direction and policy initiatives for driving medical innovation, including measures to enhance the regulation of drugs and medical devices, and clinical trial development.