For discussion on
8 November 2024

Legislative Council Panel on Health Services

Reform the Approval Mechanism for Drugs and Medical Devices and Related Staffing Arrangements

Purpose

The paper briefs Members on the policy initiatives relating to the reform of the approval mechanism for drugs and medical devices as announced in the 2024 Policy Address, and seeks Members' views on the proposed creation of four permanent directorate posts/non-civil service positions in the Department of Health (DH) for the establishment and operations of the Hong Kong Centre for Medical Products Regulations (CMPR).

Developing Hong Kong into an International Health and Medical Innovation Hub

2. The Hong Kong Special Administrative Region (HKSAR) has an efficient healthcare system. It is one of the places with the highest life expectancy worldwide. The National 14th Five-Year Plan proposes to develop HKSAR into an international innovation and technology hub. Health and medical innovation can bring the benefits of good drugs and research and development (R&D) to Hong Kong. Through innovative R&D and more drug registrations, our citizens may benefit from some of the most advanced, effective and up-to-date drugs with reduced price. The translation of innovative technologies into clinical applications can benefit the public and further contribute to the development of the industry.

3. The Chief Executive announced in the 2023 Policy Address that the HKSAR would enhance the evaluation and approval mechanism for drugs, and set up the CMPR, with the long-term objective of establishing an internationally recognised authority that registers drugs and medical devices under the "primary evaluation"[1] approach. This will help

[1] "Primary evaluation" involves the assessment of primary data and information of all pre-clinical studies (i.e. animal testing), clinical studies, manufacturing and quality control in order to fully evaluate the safety, efficacy and quality of a medicine.

accelerate the clinical use of new drugs and medical devices, and drive the development of industries relating to the R&D and testing of medical products. The main tasks include –

(a) "1+" mechanism for approval of new drugs (the "1+" mechanism): The HKSAR Government has established the "1+" mechanism. It was launched on 1 November 2023 and extended to all new drugs on 1 November 2024. Under the "1+" mechanism, holders of registration from one (instead of two or more) of the recognised drug regulatory authorities for new drugs could apply for registration in the HKSAR, on the condition that they could provide local clinical data which complies with the requirements and information recognised by local experts. Apart from enabling good drugs for use in Hong Kong, the "1+" mechanism, with its requirement of local clinical data and expert endorsement for registration (i.e. the "+" in "1+"), will continue to ensure that all drugs approved for registration meet the stringent safety, efficacy and quality requirements, strengthen the local drug approval capacity, and facilitate the development of related hardware, software and human resources;

(b) International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH): The ICH is an international authoritative organisation whose current membership includes the drug regulatory authorities of Mainland China, Europe, Switzerland, the United Kingdom and the United States, where "primary evaluation" takes place. Its purpose is to co-ordinate the technical requirements for registration of medicines among its members and to develop guiding principles for the highest international standards of safety, efficacy and quality. We have become an ICH observer under the name of Hong Kong, China in end 2023. This allows the HKSAR to familiarise with the latest development of drug regulation and to enhance the local drug regulatory regime, so as to further align HKSAR with the WHO-Listed Authority, with a view to striving to become an ICH regulatory member[2] and gain international recognition for drugs approved in the HKSAR; and

[2] Based on international experience, it usually takes about eight to ten years from initial engagement with the ICH to becoming an ICH regulatory member.

(c) CMPR: The HKSAR Government will comprehensively consolidate and implement the current regulatory and approval regimes of drugs (including both Chinese medicines and Western medicines) and medical devices in the HKSAR. Meanwhile, we will implement primary evaluation of drugs and medical devices, i.e. to approve applications for registration of medical products in the HKSAR independently based on clinical data, without relying on other drug regulatory authorities. In this connection, the DH established the Preparatory Office for the CMPR on 5 June 2024 to facilitate the establishment of the CMPR and strengthen the current regulatory and approval regimes for drugs and medical devices.

4. At the same time, clinical trial is an important process in translating clinical research into marketing authorisation and clinical application. The HKSAR has high-quality healthcare professions, and a considerable amount of high-quality research data generated by local clinical trials over the years, which are widely recognised by drug regulatory authorities both on the Mainland and abroad. After the announcement of the 2023 Policy Address, the "Greater Bay Area International Clinical Trial Institute" (GBAICTI) is anticipated to come into full operation in the fourth quarter of this year in the Hetao area. The GBAICTI will serve as a one-stop clinical trial support platform to co-ordinate and integrate clinical trial resources in Hong Kong's public and private sectors, and collaborate with the "Greater Bay Area International Clinical Trial Centre" in Shenzhen to give impetus to the development of clinical trials in Hong Kong and the Guangdong-Hong Kong-Macao Greater Bay Area (GBA).

Reform the Approval Mechanism for Drugs and Medical Devices

Current Situation

5. Under the Pharmacy and Poisons Ordinance (Cap. 138), pharmaceutical products must satisfy the criteria of safety, efficacy and quality for registration before they can be sold or supplied in Hong Kong. Hong Kong has been adopting the "secondary evaluation" approach in approving applications for registration of new drugs. Specifically, this approach relies on the approvals from recognised competent drug regulatory authorities in other places which have conducted "primary evaluation". Applicants for registration of new drugs in Hong Kong are

required to provide necessary information including documentary proof for registration issued by drug regulatory authorities of reference places[3], in order to provide supporting evidence that the safety, efficacy and quality of the medicine has been rigorously evaluated before placing in the market.

6. To enhance the drug regulatory regime, the Government has implemented the "1+" mechanism with key developments set out below –

(a) launched the "1+" mechanism on 1 November 2023. Pharmaceutical products containing new chemical or biological entities for life-threatening or severely debilitating diseases that are supported with local clinical data and scope of application recognised by local relevant expert are only required to submit approval from one reference drug regulatory authority (instead of the two or more) and could submit application for registration in Hong Kong;

(b) approved the first application under the "1+" mechanism on 7 December 2023. As at the end of October 2024, a total of five new drugs have been approved under this mechanism. These include two new drugs for treating metastatic colorectal cancer, one for treating paroxysmal nocturnal haemoglobinuria, and two new drugs for treating hypercalcaemia in patients with parathyroid carcinoma and in certain patients with primary hyperparathyroidism, bringing new hope for treatment to patients. The two new drugs for treating metastatic colorectal cancer have been moved from self-financed drugs under the Named Patient Program to the "Special Drug" category of the Hospital Authority (HA) Drug Formulary. Not only has the cost price of the drugs been reduced by nearly 30%, under specified clinical applications, patients are only required to pay standard fees of $15, greatly alleviating their financial burden. It is expected that nearly 300 cancer patients will be benefited each year; and

(c) received more than 260 enquiries from over 80

[3] There is a total of 36 recognised places listed in the Guidance Notes on Registration of Pharmaceutical Products Containing a New Chemical or Biological Entity issued by the Pharmacy and Poisons Board, including Australia, Canada, the European Union, Japan, Switzerland, the United Kingdom, the United States, and four places (mainly Mainland China, Brazil, Korea and Singapore) which were added on 1 November 2022.

pharmaceutical companies, including those from overseas and the Mainland, on the "1+" mechanism. The DH will continue to proactively promote the "1+" mechanism.

7. Separately, while there is not yet specific legislation to regulate medical devices in Hong Kong, some products are already regulated by existing pieces of legislation[4]. Making reference to the recommendation of the Global Harmonization Task Force (GHTF, now known as the International Medical Device Regulators Forum (IMDRF[5]), the HKSAR Government established the Medical Device Administrative Control System (MDACS) in 2004 as a voluntary measure to safeguard public health and pave way for implementing long-term statutory control on medical devices. The MDACS operates through a two-pronged approach, encompassing pre-market and post-market controls. It incorporates internationally accepted best practices regarding safety, quality and risk management, while allowing flexibility and capability to regulate rapidly advancing medical technology. The DH has been actively promoting MDACS to the public, the medical device trade and healthcare professionals, with an aim to protect patient safety and safeguard public health in Hong Kong, as well as to ensure the smooth transition to a statutory regulatory regime for medical device in future.

8. On the other hand, Hong Kong has also established a regulatory system for Chinese medicine. Pursuant to the Chinese Medicine Ordinance (Cap. 549) and the Import and Export Ordinance (Cap. 60), the regulatory system for Chinese medicines encompasses four aspects including licensing of Chinese medicine traders, registration of proprietary Chinese medicine (pCm), import and export control on Chinese medicine, and a monitoring system for the safety of Chinese medicines. All pCms must first be registered with the Chinese Medicines Board (CMB) under the Chinese Medicine Council of Hong Kong before they can be imported, sold or manufactured in Hong Kong. All pCms must meet the requirements on safety, quality and efficacy prescribed by the CMB for them to be registered in Hong Kong.

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[4] Depending on the characteristics and features of the products concerned, they may now be regulated by Cap. 138, Radiation Ordinance (Cap. 303), Trade Descriptions Ordinance (Cap. 362), Consumer Goods Safety Ordinance (Cap. 456) and Electrical Products (Safety) Regulation (Cap. 406G), etc.

[5] The GHTF was established in 1992 by regulatory authorities and trade representatives of the United States of America, Canada, Australia, Japan and the European Union to harmonise the standards and principles for the regulation of medical devices. It was disbanded in 2011, and a new IMDRF was formed to build on the work of the GHTF. The IMDRF aims to accelerate international medical device regulatory harmonisation and convergence, and its current members include China, Australia, Brazil, Canada, the European Union, Japan, Russia, Singapore, South Korea, the United Kingdom and the United States.

Government's Commitment

9. As announced in the 2024 Policy Address, the HKSAR Government will expedite the reform of the approval mechanism for drugs and medical devices, including –

(a) extending the "1+" mechanism since 1 November 2024. It has been extended from new drugs that are beneficial for treatment of life-threatening or severely debilitating diseases to all new drugs, including vaccines and advanced therapy products. Under the extended "1+" mechanism, new drugs used for any disease can apply for registration, with a view to improving the approval mechanism to speed up registration, further facilitating good drugs for use in Hong Kong;

(b) devising the timetable for the CMPR and the roadmap towards adoption of "primary evaluation" in the first half of 2025, as well as formulating strategies and measures to facilitate R&D of drugs and medical devices; and

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

10. In the meantime, to further develop Hong Kong into an international health and medical innovation hub, as announced in the 2024 Policy Address, the HKSAR Government will enhance Hong Kong's clinical trial capability on all fronts and facilitate the translation of innovative biomedical research results into clinical applications by –

(a) joining hands with Shenzhen to establish the GBA Clinical Trial Collaboration Platform, extending the R&D network and expediting clinical trials;

(b) establishing the Real-World Study and Application Centre to open up local health and medical databases and promote co-operation between Hong Kong and Shenzhen to integrate data generated from the "special measure of using Hong Kong-registered drugs and medical devices used in Hong Kong public hospitals in GBA". This will accelerate approval for registration of new drugs in Hong Kong, the Mainland and overseas; and

(c) supporting R&D, clinical trials and application of advanced biomedical technology in Hong Kong, attracting global top-notch innovative enterprises and research organisations to set up operation in Hong Kong.

The CMPR

Objectives

11. The establishment of CMPR can make fuller use of the existing highly efficient regulatory regime to achieve greater benefits and synergies. The CMPR could also centralise relevant expertise and optimise resource allocation, with the aim of supporting the approval of innovative medical products, promoting the scientific advancement of drugs, medical devices and medical technology, and expediting their clinical application, thereby driving the development of industries relating to the R&D as well as testing of medical products. The Preparatory Office for the CMPR was set up under the DH on 5 June 2024 to make necessary preparation for the establishment of the CMPR. The major tasks of the Preparatory Office include –

(a) to make a thorough review of other jurisdictions with medical products regulation and propose a tailor-made framework and structure suitable to Hong Kong;

(b) to assess the legislative implications including amendment of existing Ordinances and related fees and charges;

(c) to consider and secure all the necessary resources, and put forward the timetable for establishing the CMPR and the roadmap towards "primary evaluation" in the first half of 2025;

(d) to plan ahead the prerequisite internal matters (e.g. staff consultation) and external activities (e.g. trade engagement), capacity building (e.g. for enhancing compliance of industry and competency of regulators) for restructuring of the existing services and functions under the regulatory affairs;

(e) to liaise with relevant policy bureaux and other departments for the plan of establishing the CMPR and its future

collaboration and co-ordination; and

(f) to oversee the planned enhancement on drug registration such as accession to the ICH, "1+" mechanism, Good Clinical Practice (GCP) site inspection, implementation of Good Distribution Practice (GDP) and Good Pharmacovigilance Practice (GVP).

12. The CMPR will be at the forefront of transforming the medical product regulatory landscape in Hong Kong, with a mission to elevate the city's status as an international health and medical innovation hub. One of its primary functions is to enhance the drug approval process, focusing on an efficient and rigorous primary evaluation to ensure safety and efficacy. The above includes implementing advanced review systems and leveraging cutting-edge technology to streamline and expedite approvals. In addition to drug approval, the CMPR is committed to maintaining the highest standards of supply chain integrity. This involves stringent monitoring and enforcement measures to prevent substandard products from entering the market. By securing the supply chain, the CMPR ensures that patients receive only high-quality and safe medical products.

13. The CMPR will also play a pivotal role in promoting and facilitating clinical trials for innovative medical products. By creating a supportive environment and providing clear pathways for clinical trials, the CMPR will work together with the Health Bureau to attract global pharmaceutical companies and researchers to conduct their trials in Hong Kong. This not only boosts local R&D but also strengthen Hong Kong's position in the global medical research arena.

14. Currently, the regulation of Western medicines, Chinese medicines and medical devices are carried out by different services under the DH, i.e. the Drug Office (DO), the Chinese Medicine Regulatory Office (CMRO) and the Medical Device Division (MDD) of the Health Sciences and Technology Office (HSTO) respectively. The CMPR, through combining the regulatory functions of Western and Chinese medicines and medical devices under a single entity, will offer numerous advantages and synergistic effects –

(a) improving coordination and collaboration among stakeholders involved in the regulatory process, enhancing efficiency, consistency, and decision-making effectiveness;

(b) harmonising the standards across drugs and medical devices will promote consistency in safety, efficacy, quality, and performance requirements, benefiting manufacturers and consumers alike;

(c) consolidating regulatory oversight will enable a comprehensive approach to safety monitoring and post-market surveillance, leading to more effective risk mitigation strategies, early detection of safety issues, and improved patient safety;

(d) pooling resources and expertise through regulatory consolidation will optimise resource allocation, support the evaluation of innovative products, and advance scientific and technological progress in the pharmaceutical, Chinese medicine and medical device sectors; and

(e) forming a unified regulatory entity will foster innovation and patient access to new therapies by facilitating the development of innovative combination products, personalised medicine, and advanced technologies, ultimately accelerating the availability of breakthrough treatments and driving healthcare advancements.

15. Ultimately, the CMPR's comprehensive approach aims to attract pharmaceutical and medical device enterprises from around the world. By offering a world-class regulatory environment, the CMPR will support the development of cutting-edge medical products and ensure that Hong Kong's approval mechanisms are recognised both internationally and by the Mainland. This strategic vision is key to transforming Hong Kong into an international health and medical innovation hub, driving economic growth and improving healthcare outcomes.

Need for Dedicated Directorate Posts/Non-civil Service Positions Support

16. The CMPR will be established as a new division under the DH and supervised directly by the Director of Health. In view of the importance of the CMPR in developing Hong Kong into an international health and medical innovation hub, dedicated directorate support is imperative for embarking on the various tasks, and formulating and implementing the enhanced medical products regulation and approval regime under the "primary evaluation" approach. It is proposed that that the following four permanent directorate posts/non-civil service positions

be created in the CMPR of the DH from 2025-26.

(a) Controller, Public Health (D4) post/D4-equivalent NCS position (tentatively designated as Controller, CMPR)

17. The CMPR will be headed by the Controller, CMPR (Controller) who will provide visionary leadership and set the strategic direction for the CMPR. The Controller will assist the Director of Health in formulating policy for medical products which aligns with health policy, executing and reviewing the enhanced regulatory control of medical products through an integrated and holistic approach that aligns with international standards and local needs. He/she will review and determine specific objectives of regulatory standards, consider pragmatic strategy for implementation, and build up capacity for enforcement and compliance. He/she will use his/her overarching view, risk management skills and tasks prioritisation abilities to formulate streamlined regulatory and approval processes for medical product under the "primary evaluation" approach. Besides, the Controller will engage with national and global regulatory authorities to adopt the best regulatory practices and gain international recognition. The Controller will be responsible for the overall management and performance of the CMPR and ensure the use of advanced technologies in regulatory processes for efficiency and accuracy. He/she will also explore the upgrading of the CMPR into a standalone statutory body in the long run. At the preparatory stage, the key tasks of the Controller are to spearhead the establishment of the CMPR, liaise with stakeholders and overseas counterparts to secure support, engage experienced experts in different regulation areas, and formulate and introduce new legislation for the empowerment of the CMPR. Considering the breadth, complexity and difficulties of the tasks involved, it is essential to have the Controller, CMPR pitched at D4 level with strong leadership and visionary thinking to play a pivotal role in leading the team to formulate and implement an integrated regulatory framework, and steering the CMPR towards becoming a globally recognised authority in medical product regulation, ensuring safe, effective and timely access to new innovations of medical products.

(b) Assistant Director of Health (ADoH) (D2) post/ D2-equivalent NCS position (tentatively designated as Deputy Controller, CMPR)

18. The Deputy Controller, CMPR (Deputy Controller) deputises the Controller, CMPR in ensuring smooth operation of the CMPR. At the preparatory stage, apart from assisting the Controller to set up the CMPR, the Deputy Controller will conduct a thorough gap analysis review of the

current drug regulatory regime in Hong Kong and other regulatory authorities of reference, and assist the Controller in formulating and implementing an integrated and holistic approach in approving registration and regulation of medical products that is on par with the international standards. He/she will oversee the implementation of the planned enhancement of medical products registration such as accession to the ICH. The Deputy Controller will develop and introduce industry good practices (such as GCP site inspection, GDP and GVP) for the trade to follow in order to ensure high standard of safety, quality and efficacy of medical products. He/she will also conduct a review on the relevant legislations and propose legislative amendments and/or new legislation to empower the implementation of the new regulatory regime. Besides, the Deputy Controller will maintain close liaison with counterpart regulatory authorities in the GBA to support various national initiatives in the GBA. It is essential for the Deputy Controller to have a wealth of experience in drug regulation with pharmacist background to take charge of the above tasks. Currently, there is ADoH with pharmacy background in the DH. He is already fully engaged in his existing duties of overseeing the drug regulation in Hong Kong and has no spare capacity to take on the above additional workload. Therefore, it is essential for the CMPR to have an additional officer equivalent to ADoH rank (i.e. the Deputy Controller, CMPR) with extensive experience and strong managerial ability to support the Controller in achieving the CMPR's strategic goal, ensuring efficient operation and maintaining high standards in medical product regulation.

(c) Chief Pharmacist (CPharm) (D1) post/ D1-equivalent NCS position (tentatively designated as Assistant Controller (Quality and Standards))

19. At the preparatory stage, the Assistant Controller (Quality and Standards) (the AC(QS)) will develop standards and guidelines for evaluation and approval of drugs and Chinese medicine under the proposed regulatory framework of medical products. He/she will collaborate with international organisations and regulatory authorities of medical products for latest development of regulatory trends and standards and establish mechanism to recognise and rely on the regulatory decision made by other drug regulatory authorities so as to make cost effective use of resources. In addition, he/she will oversee the expert training and capacity building to ensure that staff will possess adequate professional knowledge and skills to evaluate the application for drug registration and clinical trials. Staff will be regularly kept updated of the latest global trend and standards adopted in drug regulation. The AC(QS) will take necessary preparations and measures for the accession to the ICH and serve as a representative and

contact point of the ICH. He/she will also support the GBA initiatives related to medical products development. At present, there are three CPharms in the DH who are assisting the respective ADoHs to implement, monitor and promote the regulation of drugs and Chinese medicine in Hong Kong. As they are already fully engaged in their existing responsibilities, it is not feasible for them to absorb the above extra duties without affecting the quality of services they are providing. Therefore, it is vital for the CMPR to have another officer equivalent to CPharm rank (i.e. the Assistant Controller (Quality and Standards)) with sound expert knowledge and solid leadership to execute the above responsibilities, especially the development and implementation of standards that could gain international recognition on the products approved under the "1+" mechanism and future primary evaluation, so as to ensure the high standards in drug evaluation and approval, thus contributing to public health and safety.

(d) Chief Electronics Engineer (CEE) (D1) post/ D1-equivalent NCS position (tentatively designated as Assistant Controller (Medical Device))

20. Pursuant to the 2024 Policy Address, the Government is working on a new statutory regulatory framework which will empower the CMPR to ensure the safety and quality of medical device for better protection of public health. The Assistant Controller (Medical Device) (the AC(MD)) will carry out the necessary preparatory work for a smooth transition from the current voluntary MDACS to the statutory system. He/she will also be responsible for research programmes related to medical devices, classifications, new technologies, risk assessment, complex system integration, networking, collaboration, safety and performance standards, and new regulatory and control measures of medical devices, so as to prepare for enactment of the new statutory framework. He/she will support formulation of new policies and strategies in relation to statutory controls of medical devices and will ensure smooth implementation of these controls. In addition, the AC(MD) will plan for establishing primary evaluation and relevant licensing policies for new medical devices; taking into account the harmonisation of national and international requirements. The CMPR requires extensive technical knowledge and strong leadership of the AC(MD) to ensure effective planning and implementation, rigorous evaluation, engagement and collaboration with industry stakeholders, and successful promotion of the safety and quality of medical devices.

21. The proposed directorate posts will lead and complete the various

critical preparatory tasks necessary for the timely establishment of the CMPR. After establishment, the directorate posts will continue to provide crucial leadership to steer the development of the CMPR. It is proposed the four directorate posts be created as civil service posts or non-civil service positions to ensure high-calibre candidates with the appropriate set of expertise be engaged to suit the development needs of the CMPR. In order to establish, steer and develop the CMPR into an internationally renowned drug regulatory authority, the directorate staff of CMPR, who will be entrusted with the responsibility of steering and leading the innovation in regulation of medical products, are required to possess wide ranges of knowledge and expertise at different levels including, to name a few, risk/benefit analysis of medical products, pharmaceutical sciences, international good practice principles, pharmacology, clinical trial as well as an in-depth understanding of national and international drug regulatory standards and their enforcement, and awareness and understanding of emerging advancement in biomedical technology. They should also be competent in stakeholder engagement and risk and crisis management, and possess extensive networks to promote the CMPR through international and national collaborations. The proposed creation of the directorate posts as civil service posts or non-civil service positions will provide the DH with necessary flexibility to tap the expertise required, whether inside or outside the Government, to meet the need of the CMPR which may have different focuses at various stages of development.

22. The creation of the above four directorate posts/non-civil service position, if approved, will be offset by deletion of four Consultant (D2/D3/D4) posts in the DH. The proposed job description of these directorate posts is at **Annexes A to D**.

Non-directorate Support for the Preparatory Office

23. The Preparatory Office for setting up the CMPR was set up in June 2024 for supporting the smooth establishment and operation of the CMPR in the initial years. Current, the Preparatory Office is supported by six time-limited civil service posts, namely one Senior Pharmacist, one Senior Electronics Engineer, one Senior Chemist, two Pharmacists and one Scientific Officer (Medical) and 39 Non-civil Service Contract/Post-retirement Service Contract staff. The existing structure of the Preparatory Office is at **Annex E**.

Re-organisation of Services

24. Upon establishment of the CMPR, it is planned that the functions in relation to the regulation of drugs, Chinese medicine and medical devices of these services be consolidated and re-organised to be placed under the supervision of the new Controller for the CMPR. The proposed set up of the CMPR is at **Annex F**. The DH will review the above preliminary structure, and manpower and financial resources required nearer the time of setting up the CMPR. Efforts will be made to identify areas for cost saving and improving efficiency through internal redeployment and re-prioritisation of work. Additional resources, if necessary, will be sought through established mechanism.

25. Separately, as announced in the 2024 Policy Address, to enhance the health of the people of Hong Kong, improve healthcare protection and quality, and capitalise on our healthcare professions' strengths, the Government will conduct a comprehensive review on the positioning and objectives of the healthcare system. The review will cover the reforming the functions and division of work among the HA, the DH and the Primary Healthcare Commission, strengthening health promotion and disease prevention in primary healthcare, and improving public healthcare services.

Alternative Considered

26. The HKSAR Government have critically considered whether the present set-up of the DH could take forward the new initiatives and whether the existing staff complement could cope with the increasing workload. Having regard to the portfolio and workload of the existing directorate officers, the HKSAR Government consider it not feasible without affecting the quality of their work as all of these officers are fully engaged in their respective duties.

Financial Implications

27. The proposed creation of the four permanent directorate posts/non-civil service position will be offset by the deletion of four permanent Consultant (D2/D3/D4) posts in DH. There will be savings of $1,027,100 in notional annual salary cost at mid-point and $2,378,576 in full annual average staff cost (including salaries and staff on-cost). The HKSAR Government will include the necessary provision in the 2025-26 draft Estimates and reflect the resources required in the Estimates of the subsequent years.

Post	Rank	No. of post	Notional annual salary cost at mid-point ($)	Full annual average staff cost ($)
Controller	Controller, Public Health	1	3,177,120	4,483,272
Deputy Controller	ADoH	1	2,480,040	3,277,224
AD(QS)	CPharm	1	2,088,840	2,901,732
AC(MD)	CEE	1	2,088,840	2,798,124
	Consultant (for offsetting)	(4)	(10,861,940)&	(15,838,928) &
	Total	**0**	**(1,027,100)** &	**(2,378,576)** &

& Figures in bracket denotes savings

Advice Sought

28. Members are invited to note the content of this paper and give their views on the staffing proposal. Subject to Members' views, the Government will submit the above staffing proposal to the Establishment Subcommittee for recommendation to the Finance Committee for approval.

Health Bureau
Department of Health
November 2024

Annex A

Proposed Job Description for the Post of
Controller, Centre for Medical Products Regulation

Rank	**:**	**Controller, Public Health (D4)/ D4-equivalent NCS position**
Responsible to	**:**	**Director of Health**

Major duties and responsibilities

(a) To formulate, execute and review the enhanced regulatory control of medical products through an integrated and holistic approach that aligns with international standards and local needs;

(b) To maintain close liaison with national regulatory agencies and international organisations of medical products and to keep abreast of the latest global regulatory landscape of medical products so as to ensure the regulatory system of Hong Kong is on par with international standards;

(c) To formulate and execute a plan for the timely establishment of the CMPR;

(d) To liaise with various stakeholders in the GBA and to support the development of Hong Kong into an international innovation hub in the area of medical products;

(e) To support the Government on medical products development and regulation initiatives, including the legislation/legislative amendments on control of medical products;

(f) To explore the upgrading of the CMPR into an independent statutory body; and

(g) To steer and oversee the management and development of the CMPR.

Annex B

Proposed Job Description for the Post of
Deputy Controller, Centre for Medical Products Regulation

Rank	**:**	**Assistant Director of Health (D2)/ D2-equivalent NCS position**
Responsible to	**:**	**Controller, Centre for Medical Products Regulation**

Main duties and responsibilities

(a) To assist the Controller for CMPR in implementing quality management system for regulation of medical products which includes studying and updating the evaluation standards (e.g. ICH guidelines) and review practices (e.g. Good Review Practice) for medical products as well as other supporting functions that align with internationally recognised practices and standards;

(b) To assist the Controller for CMPR in conducting review on the relevant legislations and to keep abreast of global regulatory development and enhancement (e.g. Good Regulatory Practice) for proposing legislative amendments and/or new legislation to facilitate medical products regulation and robustness of regulatory system;

(c) To put forward proposals and steps for the timely establishment of the CMPR and to implement quality assurance measures to ensure its regulatory integrity, efficiency and transparency;

(d) To develop and implement Good Clinical Practice site inspection, Good Distribution Practice and Good Pharmacovigilance Practice;

(e) To maintain close liaison with various stakeholders to promote regulatory best practices and to support various national initiatives relating to drug regulation in GBA;

(f) To participate in international regulatory forums and to work with global counterparts to harmonise regulatory standards and facilitate the exchange of information; and

(g) To communicate regulatory decisions and policies to the public, healthcare professionals, and industry stakeholders to ensure transparency and trust.

Annex C

Proposed Job Description for the Post of Assistant Controller (Quality and Standards)

Rank	**:**	**Chief Pharmacist (D1)/ D1-equivalent NCS position**
Responsible to	**:**	**Deputy Controller, Centre for Medical Products Regulation**

Main duties and responsibilities

(a) To develop standards and guidelines for evaluation, approval and regulation of drugs and Chinese medicine under the proposed regulatory framework of medical products;

(b) To oversee the expert training and capacity building programmes to ensure that staff will be equipped with adequate professional knowledge and skills required for implementing the proposed regulatory framework;

(c) To take necessary preparations and measures for the accession to the ICH and serve as a representative and contact point of ICH;

(d) To establish protocol for Good Clinical Practice site inspection and to liaise with NMPA regarding site accreditation of clinical trials in Hong Kong;

(e) To assist in liaising with relevant Government departments on the provision of quality testing services required to support the CMPR; and

(f) To support GBA initiatives related to medical products development.

Annex D

Proposed Job Description for the Post of Assistant Director (Medical Device)

Rank	**:**	**Chief Electronic Engineer (D1)/ D1-equivalent NCS position**
Responsible to	**:**	**Deputy Controller, Centre for Medical Products Regulation**

Main duties and responsibilities

(a) To assist in formulating policies and strategies in relation to development of the regulatory control on medical devices;

(b) To steer the launching of research programmes related to medical devices, classification, new technologies, safety and performance standards, and new regulatory control measures of medical devices, so as to prepare for the enactment of the new medical device legislation;

(c) To plan new medical device registration and licensing policies, taking into account the harmonisation of national and international requirements; and to work with the relevant Committees to be formed, for the development, review and smooth implementation of statutory control on medical devices;

(d) To oversee the development, preparation, and implementation of the statutory controls of medical devices;

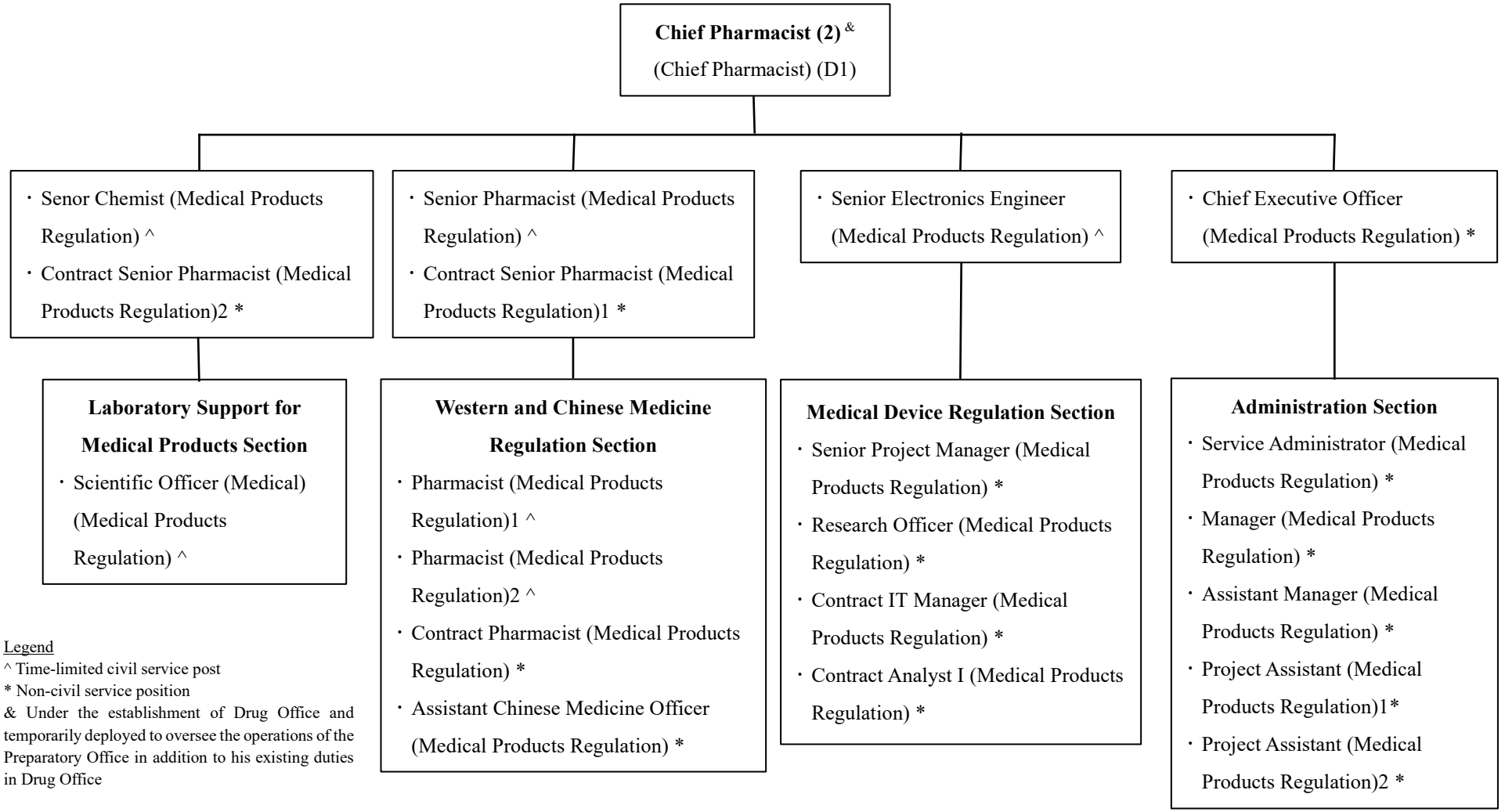
(e) To manage development and operation of the information technology systems for regulation of medical devices;

(f) To assist in professional development of staff; and setting up of quality assurance programmes for medical device regulation; and

(g) To liaise with stakeholders in regard to preparation and transition arrangements for the statutory control of medical devices.

Annex E

Organisation Chart of the Preparatory Office for CMPR

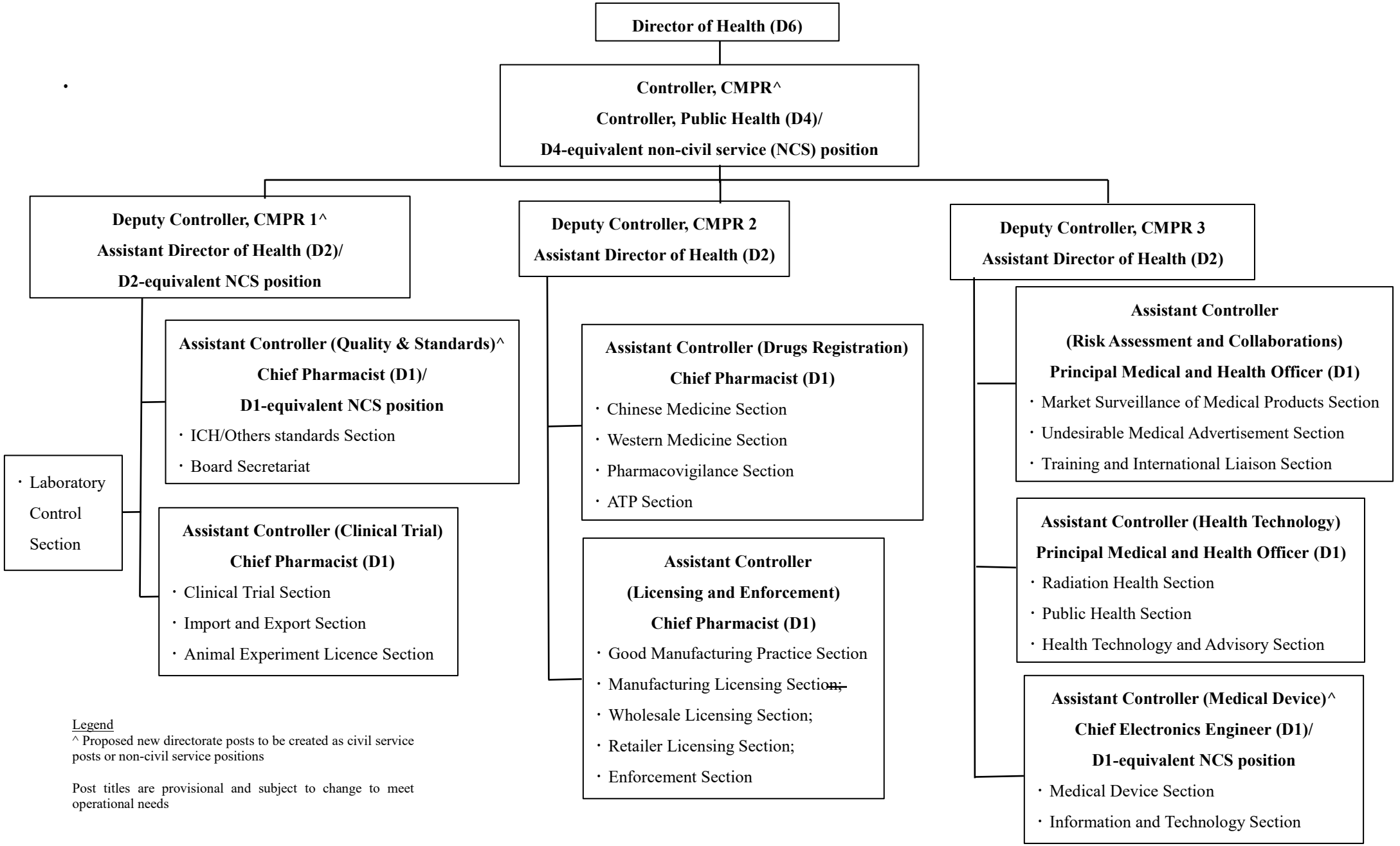


Legend
^ Time-limited civil service post
* Non-civil service position
& Under the establishment of Drug Office and temporarily deployed to oversee the operations of the Preparatory Office in addition to his existing duties in Drug Office

Note
Deployment/recruitment of other contract staff is underway

Annex F

Proposed Organisation Chart of the Set Up of the CMPR



Legend
^ Proposed new directorate posts to be created as civil service posts or non-civil service positions

Post titles are provisional and subject to change to meet operational needs