For discussion **EC(2024-25)11**
on 12 February 2025

ITEM FOR ESTABLISHMENT SUBCOMMITTEE OF FINANCE COMMITTEE

Head 37 – DEPARTMENT OF HEALTH
Subhead 000 Operational expenses

Members are invited to recommend to the Finance Committee the following proposals for the Department of Health to support the establishment and operation of the Hong Kong Centre for Medical Products Regulation –

(a) the creation of the following four permanent posts/non-civil service positions within six months from the date of approval by the Finance Committee –

1 Controller, Public Health/D4-equivalent non-civil service position
(D4) ($256,985 - $272,745)

1 Assistant Director of Health/D2-equivalent non-civil service position
(D2) ($194,825 - $212,900)

1 Chief Pharmacist/D1-equivalent non-civil service position
(D1) ($163,925 - $179,425)

1 Chief Electronics Engineer/D1-equivalent non-civil service position
(D1) ($163,925 - $179,425)

/(b) …..

(b) the deletion of the following permanent posts upon the creation of the posts under (a) above –

4 Consultants
(D2/D3/D4) ($194,825 - $212,900/$226,445 - $247,200/$256,985 - $272,745); and

(c) the redeployment of the following seven permanent posts among the directorate posts in the Department of Health to support the Hong Kong Centre for Medical Products Regulation –

2 Assistant Director of Health
(D2) ($194,825 - $212,900)

3 Chief Pharmacist
(D1) ($163,925 - $179,425)

2 Principal Medical and Health Officer
(D1) ($163,925 - $179,425)

PROBLEM

The Department of Health (DH) needs dedicated directorate support for the establishment and operations of the Hong Kong Centre for Medical Products Regulation (CMPR).

PROPOSAL

2. We propose to create, within six months from the date of approval by the Finance Committee (FC), the following four permanent posts/non civil-service (NCS) positions to provide dedicated leadership to support the establishment and operations of the CMPR with a view to implementing the "primary evaluation"[1] approach for the evaluation and approval of medical products including Western and Chinese medicines, and medical devices –

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[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.

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

(b) One Assistant Director of Health (D2) post/D2-equivalent NCS position to be tentatively designated as Deputy Controller (Medical Product Development and Standards);

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

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

3. We also propose to delete, upon the creation of the four permanent posts in paragraph 2, four permanent civil service posts of Consultant (D2/D3/D4) in the DH. Moreover, we will redeploy seven existing permanent directorate posts (at D2 and D1 ranks) which are currently leading various regulatory functions in different divisions/branches of the DH to the establishment of the CMPR in order to streamline and rationalise the relevant regulatory functions that will come under the responsibility of the CMPR.

4. The recommendations in paragraphs 2 to 3 above, made on the basis that there will be no net increase in manpower, will not involve any changes to the civil service establishment ceilings. The total directorate headcount on DH's establishment will remain unchanged.

JUSTIFICATION

Developing Hong Kong into an International Health and Medical Innovation Hub

5. 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 steered the development of 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.

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6. 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 the CMPR as an internationally recognised authority that registers drugs and medical devices under the "primary evaluation" approach. This will help 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 leading to that end include –

(a) Launching the "1+" mechanism for approval of new drugs (the "1+" mechanism): 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 Hong Kong, 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, at the same time help strengthening Hong Kong's drug approval capacity, and facilitate the development of related hardware, software and human resources;

(b) Accession to 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. Hong Kong, China has become an ICH observer 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

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

(c) Establishing CMPR: The Government will comprehensively consolidate and strengthen the regulatory and approval regimes of drugs (including Western and Chinese medicines) and medical devices under the prospective CMPR. The CMPR will implement primary evaluation of drugs and medical devices, i.e. to approve applications for registration of medical products in Hong Kong 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.

7. Clinical trial is an important process in translating clinical research into marketing authorisation and clinical application. Hong Kong 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) was officially opened on 21 November 2024 in the Hong Kong Park of the Hetao Shenzhen-Hong Kong Science and Technology Innovation Co-operation Zone. 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 Trials Centre" in Shenzhen to give impetus to the coordinated development of clinical trials in Hong Kong and the Guangdong-Hong Kong-Macao Greater Bay Area (GBA).

The Regulatory Landscape

8. 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 used to be taking 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

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[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 (namely Mainland China, Brazil, Korea and Singapore) which were added on 1 November 2022.

order to provide supporting evidence that the safety, efficacy and quality of the medicine has been rigorously evaluated before placing in the market.

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

(a) The Government launched the "1+" mechanism on 1 November 2023 and widened its applicability on 1 November 2024 to all new drugs. Pharmaceutical products containing new chemical or biological entities 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) to apply for registration in Hong Kong;

(b) As at the end of December 2024, a total of nine new drugs have been approved under this mechanism. These include two new drugs for treating metastatic colorectal cancer, one for treating paroxysmal nocturnal haemoglobinuria, two new drugs for treating hypercalcaemia in patients with parathyroid carcinoma and in certain patients with primary hyperparathyroidism, two new drugs for treating patients with anaemia caused by chronic kidney disease, and two new drugs for treating patients with extensive-stage small cell lung cancer, bringing new hope for treatment to patients. The two new drugs for treating metastatic colorectal cancer have been listed in the "Special Drug" category of the Hospital Authority (HA) Drug Formulary. Not only has the procurement cost of the drugs been reduced by nearly 30% after price negotiation, but patients are only required to pay standard fees of $15 if prescribed under specified clinical applications, greatly alleviating their financial burden. It is expected that nearly 300 cancer patients will be benefited each year; and

(c) The DH received more than 360 enquiries from over 100 pharmaceutical companies, including those from overseas and the Mainland, on the "1+" mechanism. The DH will continue to proactively promote the "1+" mechanism.

10. The Government is working on specific legislation to regulate medical devices in Hong Kong, some products are already regulated by existing pieces of legislations[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 Government established the Medical Device Administrative Control System (MDACS) in 2004 as a voluntary measure to safeguard public health and to 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.

11. Hong Kong has also established a regulatory system for Chinese medicines. 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 medicines traders, registration of proprietary Chinese medicines (pCm), import and export control on Chinese medicines, 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.

12. As announced in the 2024 Policy Address, the Government will expedite the reform of the approval mechanism for drugs and medical devices. The Government will set out the timetable for the CMPR and the roadmap towards adoption of "primary evaluation" in the first half of 2025, as well as formulate strategies and measures to facilitate R&D of drugs and medical devices.

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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), 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.

13. In the meantime, to further develop Hong Kong into an international health and medical innovation hub, as announced in the 2024 Policy Address, the Government will enhance Hong Kong's clinical trial capability on all fronts and will facilitate 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

14. 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 has been 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;

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(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).

15. 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.

16. 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.

17. 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 medicines, and advanced technologies, ultimately accelerating the availability of breakthrough treatments and driving healthcare advancements.

18. 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.

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Need for Dedicated Directorate Posts/NCS Positions Support

19. 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/NCS positions be created in the CMPR of the DH in 2025-26.

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

20. 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.

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(b) Assistant Director of Health (ADoH) (D2) post/ D2-equivalent NCS position (tentatively designated as Deputy Controller (Medical Product Development and Standards))

21. The Deputy Controller (Medical Product Development and Standards) (DC(MPD&S)) 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 DC(MPD&S) 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 DC(MPD&S) 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 DC(MPD&S) will maintain close liaison with counterpart regulatory authorities in the GBA to support various national initiatives in the GBA. It is essential for the DC(MPD&S) to have a wealth of experience in drug regulation with pharmacist background to take charge of the above tasks. Currently, there is an 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 DC(MPD&S)) 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))

22. At the preparatory stage, the Assistant Controller (Quality and Standards) (AC(QS)) will develop standards and guidelines for evaluation and approval of Western and Chinese medicines 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

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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 Western and Chinese medicines 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 AC(QS)) 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))

23. 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) (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.

24. 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 NCS 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 NCS 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.

25. The proposed job description of these directorate posts is at Enclosures 1 to 4.

Encls. 1 - 4

Non-directorate Support for the Preparatory Office

26. 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. Currently, the Preparatory Office is headed by a supernumerary Assistant Director of Health post and supported by six time-limited civil service posts[6], 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 Enclosure 5.

Encl. 5

/Re-organisation …..

[6] The creation of the six time-limited non-directorate posts were offset by the deletion of six permanent non-directorate posts.

Re-organisation of Services Relating to Medical Products Regulation

27. Upon establishment of the CMPR, it is planned that the functions in relation to the regulation of drugs, Chinese medicines and medical devices of these services be consolidated and re-organised to be placed under the supervision of the new Controller for the CMPR. Apart from the proposed four directorate posts, another seven existing directorate posts (including two ADoHs, three CPharms and two Principal Medical and Health Officers (PM&HO)) currently working in the DO, CMRO and HSTO will be redeployed to support the Controller. Their duties will be reshuffled and revised as follows to meet the operational needs of the CMPR –

(a) Deputy Controller (Drug Registration and Regulation) (DC(DR&R)) (existing Assistant Director (Drug))

28. The DC(DR&R) will oversee the registration of both pharmaceutical products and proprietary Chinese medicines and their post-market pharmacovigilance. He/she will also be responsible for the licensing and practicing control of the traders of pharmaceutical products, Chinese herbal medicines and proprietary Chinese medicines to upkeep a comprehensive strategy for an effective and efficient regulatory regime in the control of medicines and traders that is on par with international standard for the safeguard of public health.

(b) Deputy Controller (Medical Device and Technology) (DC(MD&T)) (existing Assistant Director (Health Sciences and Technology))

29. The DC(MD&T) will oversee the legislation process of the new Medical Device Bill and its implementation after enactment. He/she will also steer the planning and execution of regulatory control of medical devices, including both pre-market and post-market controls and promulgation of medical device regulatory excellence through collaboration with national, local and international agencies.

(c) Assistant Controller (Clinical Trial) (AC(CT)) (existing Chief Pharmacist (2))

30. The AC(CT) will assist in the planning and implementation of various regimes for issuance of clinical trial and medicinal test certificates and animal experiment licence, and to manage the issuing of import and export permits for pharmaceutical products and specified Chinese medicines.

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(d) Assistant Controller (Drugs Registration) (AC(DR)) (existing Chief Pharmacist (Chinese Medicine))

31. The AC(DR) will mainly assist in the planning and implementation of drug registration regimes and pharmacovigilance of pharmaceutical products and Chinese medicines for achieving regulatory efficiency and transparency as well as executing risk management and communication. He/she will also harmonise and integrate the requirements and standards for assessing the safety, quality and efficacy of pharmaceutical products and Chinese medicines.

(e) Assistant Controller (Licensing and Enforcement) (AC(L&E)) (existing Chief Pharmacist (1))

32. The AC(L&E) will assist in the planning and implementation of various regimes for licensing of traders and promoting good practices (e.g. Good Manufacturing Practice, Good Distribution Practice, and Good Pharmacy Practice) and to ensure enforcement of relevant legislative and practising requirements related to the sales of medicines. He/she will also harmonise and integrate the requirements and standards for enhancing the traceability of supplied medicines and to derive appropriate follow up actions

(f) Assistant Controller (Risk Assessment and Collaborations) (AC(RA&C)) (existing PM&HO (Medical Device))

33. The AC(RA&C) will oversee market surveillance of medical products and liaise with relevant regulatory authorities as well as stakeholders in the trade on risk communication of events related to market surveillance. He/she will also screen and monitor the undesirable advertisements and be responsible for training and international liaison.

(g) Assistant Controller (Health Technology) (AC(HT)) (existing PM&HO (Health Technology and Advisory))

34. The AC(HT) will keep abreast of the latest developments on health technologies and health sciences to assist in the planning of new regulatory regimes for medical product or health technology. He/she will also provide professional advice on the use of IT, innovation and data analytics and to advise on the corresponding business transformations.

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Encl. 6

Encls. 7 - 13

Encl. 14

35. The proposed set up of the CMPR is at Enclosure 6 and detailed revised job descriptions of the seven directorate posts which will be redeployed to the CMPR are at Enclosures 7 to 13. In addition to the seven directorate posts, about 420 existing non-directorate posts will also be redeployed to support the operations of the CMPR. Extracted part of the DH organisation chart on Services related to regulation of medical products before and after the establishment of the CMPR is sat Enclosure 14. After devolving the responsibilities concerned to the Controller for the CMPR, the Controller, Regulatory Affairs (CRA) post will then take on part of the existing duties from other deputies to the Director of Health upon reforming the functions and division of work among the DH, the HA and the Primary Healthcare Commission (PHC). The existing ADoH post in charge of the CMRO will continue overseeing the secretariat services provided to the Chinese Medicine Council of Hong Kong and the Chinese Medicine Practitioner Board as well as to undertake duties from other directorate officers as a result of the review.

36. The DH will review the preliminary structure as set out in Enclosure 6, 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.

37. 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 is conducting a comprehensive review on the positioning and objectives of the healthcare system. The review will cover the reform of functions and division of work among the HA, the DH and the PHC, strengthening health promotion and disease prevention in primary healthcare, and improving public healthcare services. As the Government's public health adviser and agency to discharge its regulatory and statutory functions, the DH will focus on its functions in the realm of public health. In this connection, the DH is transferring its specialist clinical services and primary healthcare services, step by step, to the HA and the PHC respectively. While the transfer of the Clinical Genetic Service (CGS) to the HA was completed in early 2024, arrangements are being made to transfer the Hospital Dental Service (HDS) from the DH to the HA within 2025-26. Following the transfer of the CGS and the HDS to the HA, the Government will arrange the deletion of four Consultant posts (one from the CGS and three from the HDS) and create four permanent directorate posts/NCS positions in the CMPR.

/**ALTERNATIVE** …..

ALTERNATIVE CONSIDERED

38. The Government has critically reviewed whether the present set-up of the DH could take forward the new initiatives and whether the existing staff complement could cope with the fundamental overhaul and enhancement of the medical product regulatory regime as outlined in paragraphs 14 to 18 above. Having regard to the portfolio and workload of the existing directorate officers, the 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

39. The proposed creation of the four permanent directorate posts/NCS position and the deletion of four permanent Consultant (D2/D3/D4) posts in DH will give rise to 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 Government will include the necessary provision in the 2025-26 Estimates and reflect the necessary resources in the Estimates of the relevant years. For non-directorate staff providing direct support to the four proposed directorate/NCS posts, they will be arranged through internal re-deployment and will not incur additional resource requirements.

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
AC(QS)	CPharm	1	2,088,840	2,901,732
AC(MD)	CEE	1	2,088,840	2,798,124
	Consultant (deletion)	(4)	(10,861,940)[&]	(15,838,928)[&]
	Total	**0**	**(1,027,100)**[&]	**(2,378,576)**[&]

& Figures in bracket denotes savings

PUBLIC CONSULTATION

40. We consulted the LegCo Panel on Health Services on the above staffing proposal on 8 November 2024. Members unanimously supported the submission of the proposal to the Establishment Subcommittee for consideration.

ESTABLISHMENT CHANGES

41. The establishment changes in the DH for the past two years are as follows –

Establishment (Note)	Number of Posts			
	Existing (as at 1 February 2025)	**As at 1 April 2024**	**As at 1 April 2023**	**As at 1 April 2022**
A	67 + (1)	67 + (1)	67 + (1)	67 + (1)
B	1 464	1 455	1 440	1 436
C	5 468	5 407	5 410	5 427
Total	**6 999 + (1)**	**6 929 + (1)**	**6 917 + (1)**	**6 930 + (1)**

Note –

A – ranks in the directorate pay scale or equivalent
B – non-directorate ranks, the maximum pay point of which is above MPS Point 33 or equivalent
C – non-directorate ranks, the maximum pay point of which is at or below MPS Point 33 or equivalent
( ) – number of time-limited directorate post(s) approved by the ESC/FC

CIVIL SERVICE BUREAU COMMENTS

42. The Civil Service Bureau supports the proposed creation, deletion and redeployment of the relevant permanent directorate posts/NCS positions in the DH. The grading and ranking of the proposed posts are considered appropriate having regard to the level and scope of responsibilities and professional inputs required.

43. The Government has maintained zero-growth in the civil service establishment since 2021-22, with the overall establishment contained at a level not exceeding that as at end-March 2021. The proposal contained in this paper will not affect the policy of maintaining zero-growth in the civil service establishment.

/**ADVICE** …..

ADVICE OF THE STANDING COMMITTEE ON DIRECTORATE SALARIES AND CONDITIONS OF SERVICE

44. The Standing Committee on Directorate Salaries and Conditions of Service has advised that the grading proposed for the posts is appropriate.

Health Bureau
Department of Health
February 2025

Enclosure 1 to EC(2024-25)11

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

Main duties and responsibilities

1. 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;

2. 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;

3. To formulate and execute a plan for the timely establishment of the CMPR;

4. 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;

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

6. To explore the upgrading of the CMPR into an independent statutory body; and

7. To steer and oversee the management and development of the CMPR.

Enclosure 2 to EC(2024-25)11

Proposed Job Description for the Post of
Deputy Controller (Medical Product Development and Standards)

Rank : Assistant Director of Health (D2)/D2-equivalent NCS position

Responsible to : Controller, Centre for Medical Products Regulation

Main duties and responsibilities

1. 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;

2. 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;

3. 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;

4. To develop and implement Good Clinical Practice site inspection, Good Distribution Practice and Good Pharmacovigilance Practice;

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

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

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

Enclosure 3 to EC(2024-25)11

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

Rank : Chief Pharmacist (D1)/D1-equivalent NCS position

Responsible to : Deputy Controller (Medical Product Development and Standards)

Main duties and responsibilities

1. To develop standards and guidelines for evaluation, approval and regulation of Western and Chinese medicines under the proposed regulatory framework of medical products;

2. 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;

3. To take necessary preparations and measures for the accession to the ICH and serve as a representative and contact point of ICH;

4. To establish protocol for Good Clinical Practice site inspection and to liaise with the relevant drug regulatory authorities to recognize site accreditation of clinical trials in Hong Kong;

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

6. To support GBA initiatives related to medical products development.

Enclosure 4 to EC(2024-25)11

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

Rank ： Chief Electronics Engineer (D1)/D1-equivalent NCS position

Responsible to ： Deputy Controller (Medical Device and Technology)

Main duties and responsibilities

1. To assist in formulating policies and strategies in relation to development and implementation of the regulatory control on medical devices;

2. To oversee the launching and operation of research programmes related to medical devices, classification, new technologies, safety and performance standards, and new regulatory control measures of medical devices;

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

4. To oversee the development, preparation, and implementation of the statutory controls of medical devices, and to oversee the development and operation of the respective IT systems and computer projects;

5. To manage development and operation of the information technology systems, data analytics and innovation initiatives for CMPR;

6. To assist in professional development of staff; and setting up of quality assurance programmes for medical device regulation; and

7. To liaise with stakeholders regarding preparation, transition arrangements and implementation of statutory control of medical devices.

Organisation Chart of the Preparatory Office for CMPR

Assistant Director of Health
(Preparatory Office for Centre for Medical Products Regulation) & (D2)

- Senor Chemist (Medical Products Regulation) ^
- Contract Senior Pharmacist (Medical Products Regulation)2 *

Laboratory Support for Medical Products Section
- Scientific Officer (Medical) (Medical Products Regulation) ^

- Senior Pharmacist (Medical Products Regulation) ^
- Contract Senior Pharmacist (Medical Products Regulation)1 *

Western and Chinese Medicine Regulation Section
- Pharmacist (Medical Products Regulation)1 ^
- Pharmacist (Medical Products Regulation)2 ^
- Contract Pharmacist (Medical Products Regulation) *
- Assistant Chinese Medicine Officer (Medical Products Regulation) *

- Senior Electronics Engineer (Medical Products Regulation) ^

Medical Device Regulation Section
- Senior Project Manager (Medical Products Regulation) *
- Research Officer (Medical Products Regulation) *
- Contract IT Manager (Medical Products Regulation) *
- Contract Analyst I (Medical Products Regulation) *

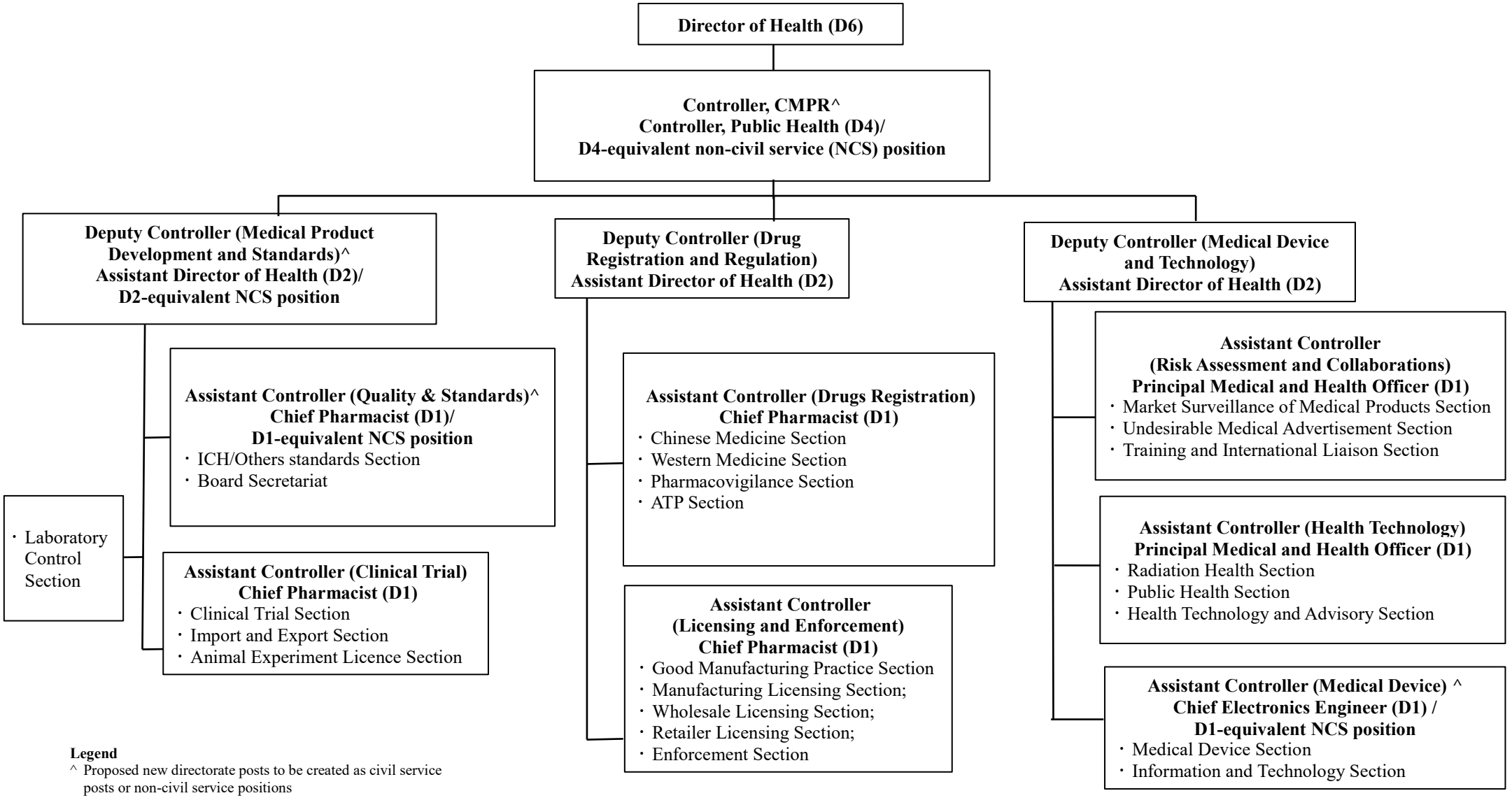
- Chief Executive Officer (Medical Products Regulation) *

Administration Section
- Service Administrator (Medical Products Regulation) *
- Manager (Medical Products Regulation) *
- Assistant Manager (Medical Products Regulation) *
- Project Assistant (Medical Products Regulation)1*
- Project Assistant (Medical Products Regulation)2 *

Legend
^ Time-limited civil service post
* Non-civil service position
& Supernumerary post

Note
Deployment/recruitment of other contract staff is underway

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

Structure and post titles are provisional and subject to change to meet operational needs

Enclosure 7 to EC(2024-25)11

Revised Job Description for the post of
Deputy Controller (Drug Registration and Regulation)
(existing Assistant Director (Drug))

Rank ： Assistant Director of Health (D2)

Responsible to ： Controller, Centre for Medical Products Regulation

Main duties and responsibilities –

1. To lead and steer the quality management for registration of pharmaceutical products and proprietary Chinese medicines and their post-market pharmacovigilance; and licensing and practicing control of the traders of pharmaceutical products, Chinese herbal medicines and proprietary Chinese medicines to upkeep a comprehensive strategy for an effective and efficient regulatory regime in the control of medicines and traders that is on par with international standard for the safeguard of public health;

2. To keep abreast of international developments on pharmaceutical and Chinese medicine matters, exchange information and maintain close communication and partnership with international and local stakeholders;

3. To spearhead initiatives in the regulatory areas including marketing authorization, pharmacovigilance, good practices and standards, risk assessment and communication to ensure safety, quality and efficacy of medicines for public health protection and promotion;

4. To provide professional support to the Bureaux, Departments and the Boards on regulation of medicines, and to chair the various Committees established under the Board for the assurance of safety and quality of medicines as well as the continuous improvement of the standard of the traders; and

5. To promote professional development and strive for quality improvement of staff members in achieving high standard of competencies for successful teamwork and excellence of performance with the goal to ensure improvement and sustainability of the service.

Enclosure 8 to EC(2024-25)11

Revised Job Description for the post of
Deputy Controller (Medical Device and Technology)
(existing Assistant Director (Health Sciences and Technology))

Rank : Assistant Director of Health (D2)

Responsible to : Controller, Centre for Medical Products Regulation

Main duties and responsibilities –

1. To lead the drafting and enactment of the new Medical Device Bill;

2. To steer the development, planning and administration of regulatory control of medical devices, including both pre-market and post-market controls;

3. To steer the development and promulgation of medical device regulatory excellence via capacity building and collaboration with national, local and international agencies;

4. To supervise the work of the Health Technology and Advisory Section, which keeps abreast of technological developments and steer business transformation of CMPR; and supports the Council on the Human Reproductive Technology and the Human Organ Transplant Board;

5. To supervise the work of the Radiation Health Section, which advises the Government on radiation health and supports the enforcement of the Radiation Ordinance and handling of the radioactive substance and irradiating apparatus licence applications;

6. To supervise the work of the Information and Technology Section of CMPR, which is responsible for development and operation of IT systems and data analytics for CMPR;

7. To supervise the Public Health Section and administration team of CMPR; and

8. To provide professional support to relevant statutory / advisory bodies and stakeholders.

Enclosure 9 to EC(2024-25)11

Revised Job Description for the post of
Assistant Controller (Clinical Trial)
(existing Chief Pharmacist (2))

Rank : Chief Pharmacist (D1)

Responsible to : Deputy Controller (Medical Product Development and Standards)

Main duties and responsibilities –

1. To oversee and manage sections of Clinical Trial, Import and Export Control and Animal Experiment Licence, and to ensure their smooth operation;

2. To assist in the planning and implementation of various regimes for issuance of clinical trial and medicinal test certificates and animal experiment licence; and to effectively manage the delegated duties of issuing import and export permits for pharmaceutical products and specified Chinese medicines;

3. To oversee the development and operation of the systems and computer projects related to application for clinical trial and medicinal test certificates, animal experiment licences and import/export permits; and to monitor the adverse events and trend of usage for deriving appropriate follow up actions;

4. To provide technical support to the relevant statutory/advisory bodies and their respective committees; and

5. To oversee the operation of the Government Chinese Medicine Testing Institute (GCMTI) and the GCMTI Advisory Committee, and to ensure the research and skill transfer activities of GCMTI would be effective and meeting the objectives of GCMTI.

Enclosure 10 to EC(2024-25)11

Revised Job Description for the post of
Assistant Controller (Drugs Registration)
(existing Chief Pharmacist (Chinese Medicine))

Rank ： Chief Pharmacist (D1)

Responsible to ： Deputy Controller (Drug Registration and Regulation)

Main duties and responsibilities –

1. To oversee and manage the Sections of Drug Registration of Western Medicines (i.e. Pharmaceutical Products including Advanced Therapy Products) and Chinese Medicines, and the Pharmacovigilance, and to ensure their smooth operation;

2. To assist in the planning and implementation of drug registration regimes and pharmacovigilance of pharmaceutical products and Chinese medicines for achieving regulatory efficiency and transparency as well as executing risk management and communication;

3. To oversee the development and operation of the systems and computer projects related to application for registration of medicines and their safety information update and dissemination;

4. To harmonise and integrate the requirements and standards for assessing the safety, quality and efficacy of pharmaceutical products and Chinese medicines; and

5. To provide technical support to the relevant statutory/advisory bodies and their respective committees.

Enclosure 11 to EC(2024-25)11

Revised Job Description for the post of
Assistant Controller (Licensing and Enforcement)
(existing Chief Pharmacist (1))

Rank ： Chief Pharmacist (D1)

Responsible to ： Deputy Controller (Drug Registration and Regulation)

Main duties and responsibilities –

1. To oversee and manage the implementation of Good Manufacturing Practice (GMP), and sections for licensing of manufacturer, wholesaler and retailer of medicines; and enforcement of relevant legislative and practising requirements related to the sales of medicines; and to ensure their smooth operation;

2. To assist in the planning and implementation of various regimes for licensing of traders and promoting good practices (e.g. Good Manufacturing Practice, Good Distribution Practice, and Good Pharmacy Practice) and to master enforcement action for strengthening regulatory compliance;

3. To oversee the development and operation of the computer systems related to application for licensing of traders;

4. To harmonise and integrate the requirements and standards for enhancing the traceability of supplied medicines and to derive appropriate follow up actions; and

5. To provide technical support to the relevant statutory/advisory bodies and their respective committees.

Enclosure 12 to EC(2024-25)11

Revised Job Description for the post of
Assistant Controller (Risk Assessment and Collaborations)
(existing Principal Medical and Health Officer (Medical Device))

Rank ： Principal Medical and Health Officer (D1)

Responsible to ： Deputy Controller (Medical Device and Technology)

Main duties and responsibilities –

1. To oversee the sections of Market Surveillance of Medical Products, Undesirable Medical Advertisement, and Training and International Liaison; to ensure their smooth operation; and to oversee the development and operation of the respective IT systems and computer projects;

2. To liaise with relevant regulatory authorities, bureaux and departments, as well as stakeholders in the trade, healthcare professionals and organisations on risk communication of events related to market surveillance;

3. To co-ordinate with other units in DH / CMPR for matters related to market surveillance of medical products matters;

4. To oversee the screening / monitoring of undesirable advertisements, and handling of relevant enquiries / complaints; and

5. To maintain liaison with the Mainland and overseas regulatory authorities and professionals; to keep abreast of the latest development on the regulation of medical products and the latest technology advancements; and to advise the capacity building plans for relevant staff as appropriate.

Enclosure 13 to EC(2024-25)11

Revised Job Description for the post of
Assistant Controller (Health Technology)
(existing Principal Medical and Health Officer
(Health Technology and Advisory))

Rank ： Principal Medical and Health Officer (D1)

Responsible to ： Deputy Controller (Medical Device and Technology)

Main duties and responsibilities –

1. To keep abreast of the latest developments on health technologies/health sciences; to advise on the corresponding change management; and to co-ordinate with other units in DH/CMPR in the planning of new regulatory regimes for medical product or health technology;

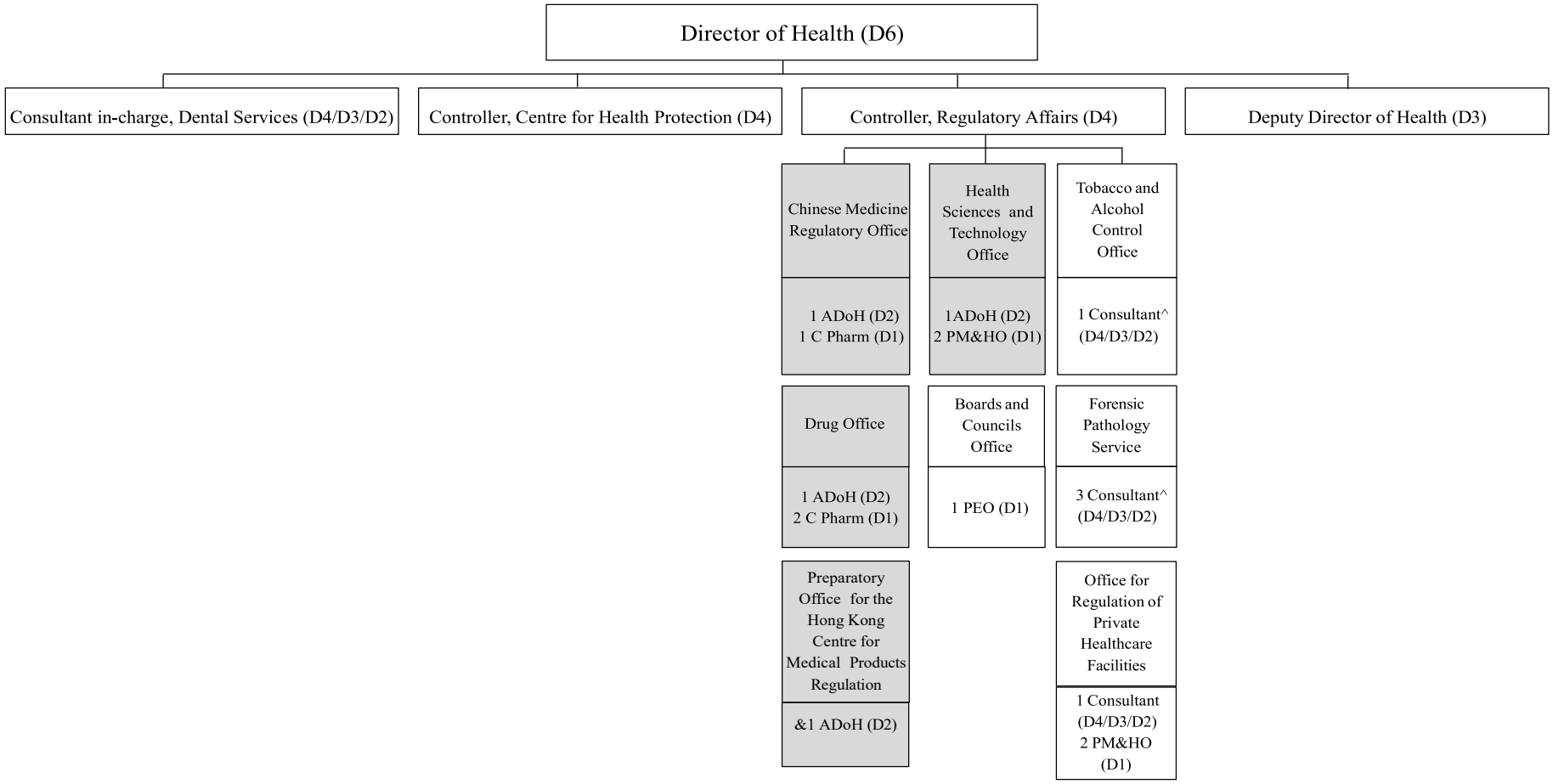
2. To provide professional advice on the use of IT, innovation and data analytics; to advise on the corresponding business transformations; and to provide public health inputs to other sections of CMPR;

3. To coordinate public health and regulatory input for technical assessment of funding applications related to health technology of relevant bureaux/ departments;

4. To oversee professional support to the Radiation Board and its committees on licensing and law enforcement matters on the local control of radioactive substances and irradiating apparatuses; import licensing; and radiation monitoring services for radiation workers; and

5. To oversee professional support to the Council on Human Reproductive Technology and its committees; Human Organ Transplant Board; and the exemption of regulated products and its post-marketing control under the Human Organ Transplant Ordinance.

Existing Organisation Chart of the Department of Health (Part) (Note)
(as at 1 February 2025)



Note

The organisation chart shows only part of the structure of the Department of Health indicating existing Services under the supervision of the Controller, Regulatory Affairs who is currently responsible for regulation of medical products. Services related to regulation of medical products are shaded in grey.

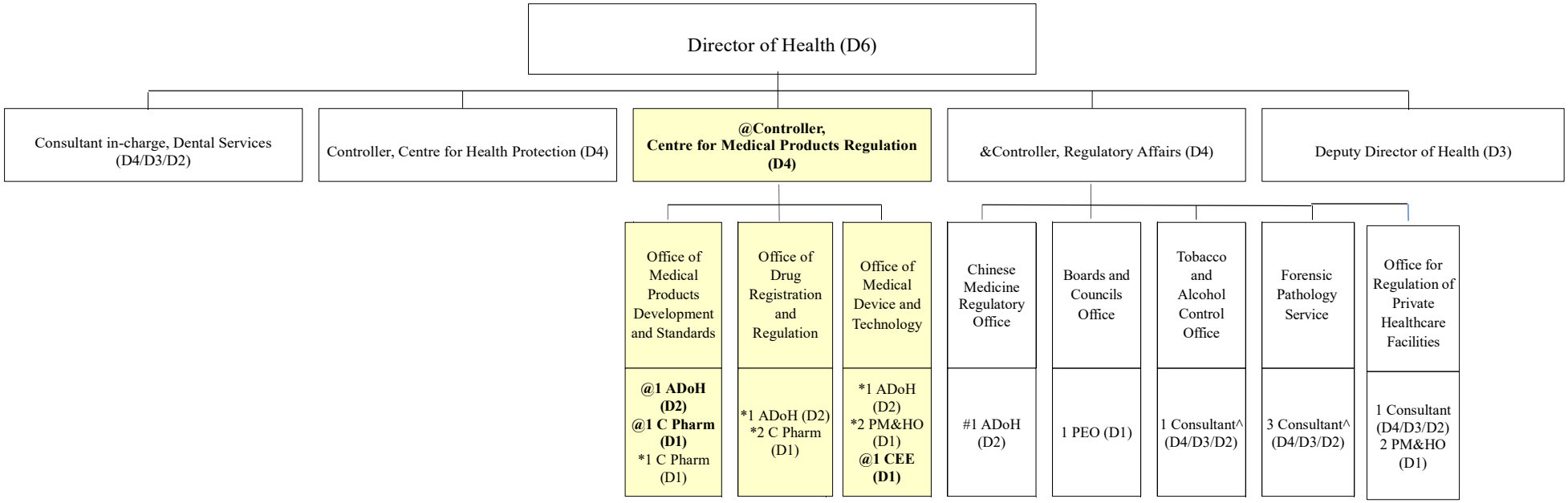
Legend

ADoH - Assistant Director of Health
C Pharm - Chief Pharmacist
PEO - Principal Executive Officer
PM&HO - Principal Medical and Health Officer

^ One Consultant post in Forensic Pathology Service is frozen for creation of one supernumerary Consultant post in the Tobacco and Alcohol Control Office

& Supernumerary post

Proposed Organisation Chart of the Department of Health (Part) (Note)



Note

The organisation chart shows only part of the structure of the Department of Health (DH) after establishment of the Hong Kong Centre for Medical Products Regulation (CMPR) and re-organisation of Services related to regulation of medical products. Changes arising from the re-organisation are shaded in yellow.

Legend

ADoH - Assistant Director of Health
CEE - Chief Electronics Engineer
C Pharm - Chief Pharmacist
PEO - Principal Executive Officer
PM&HO – Principal Medical and Health Office

@ Proposed new posts.

* Posts proposed to be re-deployed from Chinese Medicine Regulatory Office, Drug Office and Health Sciences and Technology Office (formerly under Controller, Regulatory Affairs). Upon the establishment of the CMPR, the regulatory functions in relation to drugs, Chinese medicine and medical devices of these offices will be consolidated and re-organised to be placed under the new CMPR.

& The Controller, Regulatory Affairs post will oversee the establishment and operations of the CMPR before the Controller, Centre for Medical Products Regulation post is filled. He/she will also undertake additional duties of other deputies of the Director of Health upon re-organisation of the DH which is being reviewed as announced in 2024 Policy Address. The revised scope of duties will be reported to the Establishment Subcommittee at a later stage.

\# The ADoH post will continue overseeing the secretariats of the Chinese Medicine Council and Chinese Medicine Practitioner Board, and matters related to development and regulation of Chinese medicine practitioners as well as to undertake duties from other directorate officers upon re-organisation of the DH. The revised scope of duties will be reported to the Establishment Sub-committee at a later stage.

^ One Consultant post in Forensic Pathology Service is frozen for creation of one supernumerary Consultant post in the Tobacco and Alcohol Control Office.