香港特別行政區政府
衞生署
私營醫療機構規管辦公室

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THE GOVERNMENT OF THE HONG KONG
SPECIAL ADMINISTRATIVE REGION
DEPARTMENT OF HEALTH
OFFICE FOR REGULATION OF
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Dear Licensees of Private Healthcare Facilities and Licence Applicants,

Update on Regulatory Requirements on the Use of Injectable and Infusible Products in Licensed Private Healthcare Facilities

This serves to inform all licensees and licence applicants of the updated regulatory requirements governing the **use of injectable and infusible products** in private healthcare facilities ("PHFs") licensed under the *Private Healthcare Facilities Ordinance* (Cap. 633). The updated requirements, endorsed by the Advisory Committee for Regulatory Standards for Private Healthcare Facilities, cover three product categories: **pharmaceutical products**, **human organ / human tissue products under the *Human Organ Transplant Ordinance* (Cap. 465)** and **medical devices**. Details are as follows.

I. Pharmaceutical products

Under the *Pharmacy and Poisons Regulations* (Cap. 138A), a subsidiary legislation of the *Pharmacy and Poisons Ordinance* (Cap. 138), pharmaceutical products ("PPs") must be registered with the Pharmacy and Poisons Board of Hong Kong ("the Board") before they can be sold, offered for sale, distributed or possessed for the purposes of sale, distribution or other use in Hong Kong. Import and export of PPs are subject to the control of the *Import and Export Ordinance* (Cap. 60). Where the use of an unregistered PP is necessary for the purpose of treatment by a registered medical practitioner or a registered dentist of a particular patient, the import of such PPs must be covered by a valid import licence issued under Cap. 60.

Licensed PHFs must keep complete procurement records of PPs. If the unregistered imported PPs are imported for treatment of particular patients by registered medical practitioners or registered dentists, the relevant documentation such as import licence must be retained.

For detailed classification of products as PPs, please refer to the updated *Guidance Notes on Classification of Products as "Pharmaceutical Products" under the Pharmacy and Poisons Ordinance (Cap. 138)* (April 2026) (https://www.ppbhk.org.hk/eng/doc/guidelines_forms/Guide_on_PRClass_en.pdf) issued by the Board.

II. Human organ / human tissue products under the *Human Organ Transplant Ordinance* (Cap. 465)

Products containing processed human organs or tissues for transplant purposes (e.g. skin and bone graft products) are regulated under the *Human Organ Transplant Ordinance* (Cap. 465). Before clinical use, all such products must either have been granted exemption by the Director of Health or otherwise fully comply with the statutory requirements of Cap. 465.

Apart from the regulatory requirements under Cap. 465, please be further reminded that transplant of any cell, tissue or organ is described in column 2 of Schedule 3 to the *Private Healthcare Facilities Ordinance* (Cap. 633). Therefore, injection or infusion of human organ / human tissue products (except for the procedures described in column 3 of Schedule 3 to Cap. 633) cannot be conducted in clinics under Cap. 633.

III. Medical devices

Since 2004, the Department of Health ("DH") has introduced the Medical Device Administrative Control System ("MDACS"), a voluntary listing system, to ensure that medical devices ("MDs") supplied in Hong Kong meet the safety, quality and performance requirements.

To further protect patient safety and to provide sufficient time for licensed PHFs to source compliant alternatives, the requirement that **all injectable and infusible MDs used in licensed PHFs must be listed under MDACS will take effect on 1 March 2027**. This requirement on MDs includes all injectable **dermal fillers** and injectable

mucous membrane fillers.

PHFs are strongly advised to liaise with product suppliers promptly to verify product compliance and ensure that all injectable and infusible MDs used in their facilities are listed under MDACS by the effective date.

Checking product registration / exemption status

To check whether a product is a registered PP, a regulated product exempted under Cap. 465 or a listed MD, you may consult your supplier or refer to the following official databases:

(i) Drug Office – Drug Database: https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/search_drug_database.html;
(ii) Health Technology and Advisory Division – Register of Exemptions: https://www.dh.gov.hk/english/useful/useful_hot_exemption/useful_roe.html; and
(iii) Medical Device Division – List of Medical Devices: https://www.mdd.gov.hk/en/mdacs/search-database/list-md/index.html

Summary

All injectable and infusible products used in licensed PHFs must fall within one of the following categories:

1. **Pharmaceutical products** registered under Cap. 138A (or pharmaceutical products exempted from registration under Cap. 138A, for example, imported and used for treatment of a particular patient by a registered medical practitioner or a registered dentist covered by a valid import licence issued under Cap. 60);
2. **Human organ / human tissue products** in compliance with Cap. 465; or
3. **Medical devices** listed under MDACS.

Update to codes of practice

The codes of practice ("CoPs") for private hospitals, day procedure centres and clinics will be revised to incorporate the above updated requirements. The DH intends to publish the revised CoPs in the Gazette in the **fourth quarter of 2026**. The revised CoPs, except for the sections on injectable and infusible MDs, will take effect one month

after publication in the Gazette. **The requirement for using injectable and infusible MDs listed under MDACS will take effect on 1 March 2027**.

Compliance with the CoP is a condition for the issuance and renewal of licences. Under section 47 of Cap. 633, the licensee is wholly responsible for the operation of the PHF, including ensuring full compliance with the CoP. The Director of Health may revise the CoPs from time to time; licensees are therefore advised to visit the website of the Office for Regulation of Private Healthcare Facilities (https://www.orphf.gov.hk/en/home) regularly for updates.

To facilitate a better understanding of the regulatory requirements, a set of Frequently Asked Questions is attached at the **Annex** for your reference. Should you have any enquiries, please contact the following:

Matters	**Telephone**	**Email**
Related to regulation of PHFs	3107 8451	orphf@dh.gov.hk
Related to regulation of PPs	2961 8857	pharmgeneral@dh.gov.hk
Related to regulation under Cap. 465	2961 8944	hot_rpe@dh.gov.hk
Related to listing of MDs	3107 8484	mdd@dh.gov.hk

Yours faithfully,

(Dr Joanna LEUNG)
for Director of Health

cc. Chief Medical Executives of Licensed Private Healthcare Facilities

Annex

Frequently Asked Questions

Q1	**What are the updated requirements for the use of injectable and infusible products in licensed private healthcare facilities ("PHFs")?**
A1	The Advisory Committee for Regulatory Standards for Private Healthcare Facilities has endorsed updated regulatory requirements governing the use of injectable and infusible products in licensed PHFs. All injectable and infusible products used in licensed PHFs must fall within one of the following categories: (i) **Pharmaceutical products ("PPs")** registered under the *Pharmacy and Poisons Regulations* (Cap. 138A) (or PPs exempted from registration under Cap. 138A); (ii) **Human organ / human tissue products** in compliance with the *Human Organ Transplant Ordinance* (Cap. 465); or (iii) **Medical devices ("MDs")** listed under the Medical Device Administrative Control System ("MDACS"). The codes of practice ("CoPs") for licensed PHFs will be revised accordingly. The Department of Health intends to publish the revised CoPs in the Gazette in the fourth quarter of 2026. The revised CoPs, except for the sections on MDs, will take effect one month after publication in the Gazette. The requirement for using injectable and infusible MDs listed under MDACS will take effect on **1 March 2027**.
Q1	**在持牌私營醫療機構使用注射式和輸注式製品的要求有甚麼更新？**
A1	私營醫療機構規管標準諮詢委員會已通過以下有關在持牌私營醫療機構使用注射式和輸注式製品的規管要求的更新。 所有於持牌私營醫療機構內使用的注射式和輸注式製品必須屬於以下其中一類： (i) 已根據《藥劑業及毒藥規例》（第 138A 章）註冊的**藥劑製品**（或根據第 138A 章獲豁免註冊的藥劑製品）； (ii) 符合《人體器官移植條例》（第 465 章）規定的**人體器官或人體組織產品**；或 (iii) 在醫療器械行政管理制度（MDACS）表列的**醫療器械**。 持牌私營醫療機構的實務守則將會相應地作出修訂。衞生署計劃於 2026 年第四季在憲報刊登修訂後的實務守則。除了有關醫療器械的部分，修訂後

	的實務守則將於刊憲後一個月生效。有關使用已在 MDACS 表列的注射式和輸注式醫療器械的要求將於 **2027 年 3 月 1 日**生效。
Q2	**What are the legal requirements governing the use of unregistered PPs?**
A2	Regulation 36(1A) of Cap. 138A stipulates circumstances or conditions under which possession or use of PPs could be exempted from registration. Examples are PPs possessed or to be used for treatment of a particular patient by a registered medical practitioner or a registered dentist. The import of PPs must be covered by a valid import licence issued under the *Import and Export Ordinance* (Cap. 60).
Q2	**使用未經註冊的藥劑製品有甚麼法例要求？**
A2	香港法例第 138A 章第 36(1A)條指明在何等情況或條件下管有或使用的藥劑製品可獲豁免註冊。例如，由註冊醫生或註冊牙醫為治療某特定病人而管有或將會使用的藥劑製品。藥劑製品的進口必須根據《進出口條例》（第 60 章）獲發有效的進口許可證。
Q3	**What are human organ / human tissue products in compliance with the *Human Organ Transplant Ordinance* (Cap. 465)? Can I provide them to patients?**
A3	Products containing processed human organs or tissues for transplant purposes (e.g. skin and bone graft products) are regulated under Cap. 465. Before use, registered medical practitioners and registered dentists must ensure that such products have either been granted exemption by the Director of Health or otherwise fully comply with the requirements of Cap. 465. Apart from regulation under Cap. 465, please be reminded that transplant of any cell, tissue or organ is a procedure described in column 2 of Schedule 3 to the *Private Healthcare Facilities Ordinance* (Cap. 633). Therefore, injection or infusion of human organ / human tissue products (except for the procedures described in column 3 of Schedule 3 to Cap. 633) cannot be performed in clinics. The above requirements regarding Cap. 465 and Cap. 633 are already in force and must always be observed.
Q3	**甚麼是符合《人體器官移植條例》（第 465 章）規定的人體器官或人體組織產品？我可以向病人提供這些產品嗎？**
A3	含有經加工處理的人體器官或組織、並用於移植用途的產品（例如皮膚及骨移植產品）受《人體器官移植條例》（第 465 章）規管。註冊醫生及註

	冊牙醫在使用前必須確保相關產品已獲衞生署署長豁免，或完全符合第 465 章的規定。 除第 465 章的規管要求外，請注意，移植任何細胞、組織或器官是一項《私營醫療機構條例》（第 633 章）附表 3 第 2 欄所描述的的程序。因此，人體器官或人體組織產品的注射或輸注不可在診所內進行（第 633 章附表 3 第 3 欄所描述的程序除外）。 上述有關第 465 章及第 633 章的規定均已生效，必須時刻遵守。
Q4	**Will there be a transition period for the new requirement on the use of injectable and infusable MDs in licensed PHFs?**
A4	To enhance patient safety and to provide sufficient time for licensed PHFs to source compliant alternatives, the requirement that all injectable and infusible MDs used in licensed PHFs must be listed under MDACS will take effect on **1 March 2027**. PHFs are strongly advised to liaise with product suppliers promptly to verify product compliance and ensure that all injectable and infusible MDs (including **injectable dermal fillers** and **injectable mucous membrane fillers**) used in their premises are listed under MDACS by the effective date.
Q4	**有關在持牌私營醫療機構使用注射式和輸注式醫療器械的新要求，會否設有過渡期？**
A4	為加強病人安全，並讓持牌私營醫療機構有充足時間採購已表列的替代產品，所有在私營醫療機構使用的注射式和輸注式醫療器械必須已在 MDACS 表列的要求將於 **2027 年 3 月 1 日**生效。 本署強烈建議各私營醫療機構盡快與產品供應商聯絡，以核實有關產品是否符合規定，並確保在上述生效日期或以前，所有在處所內使用的注射式和輸注式醫療器械（包括注射式皮下填充劑及注射式黏膜填充劑）均為已在 MDACS 表列的醫療器械。

- End -