

香港特別行政區政府
衛生署
香港灣仔皇后大道東 213 號
胡忠大廈 17 樓及 21 樓



THE GOVERNMENT OF THE HONG KONG
SPECIAL ADMINISTRATIVE REGION
DEPARTMENT OF HEALTH
WU CHUNG HOUSE, 17TH & 21ST FLOORS,
213 QUEEN'S ROAD EAST,
WANCHAI, HONG KONG

本署檔案 OUR REF: (38) in DH HT&A/1-60/3 Pt.2

電話 TEL: (852) 2961 8944

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6 July 2026

Dear Sir or Madam,

The Guidance for Cell and Tissue Products

Currently, advanced therapy products (“ATPs”) are regulated as pharmaceutical products for human use under the Pharmacy and Poisons Ordinance (Cap. 138). By contrast, **human cells or tissues that are subject to minimal manipulation and intended for homologous use** are generally regarded as posing lower health risk than ATPs. Nevertheless, proper handling remains essential to ensure their safe use.

The Department of Health has published the *Guidance for Cell and Tissue Products* (“the Guidance”) since 2020 to provide the industry and stakeholders with minimum requirements for maintaining quality and safety in the handling and utilisation of relevant cell and tissue products, and we are pleased to inform you that a Chinese version of the Guidance has now been released. Please refer to DH’s website at https://www.advancedtherapyinfo.gov.hk/cbb/tc/doc/Guidance_for_Cell_and_Tissue_Products.pdf or the QR code below for more details of the Guidance.



Thank you for your attention.

Yours faithfully,

(Dr Grace WONG)
for Director of Health

***We build a healthy Hong Kong and
aspire to be an internationally renowned public health authority***

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先生/女士：

《細胞及組織產品指引》

目前，先進治療產品乃依據《藥物及毒藥條例》（第 138 章）作為供人使用的藥物加以規管。相較之下，經極微程度加工並擬作同種用途的人體細胞或組織，一般被視為對健康風險較低。然而，妥善處理仍屬必要，以確保其安全使用。

衛生署自 2020 年起已發布《細胞及組織產品指引》（“《指引》”），為業界及持份者訂定最低要求，以確保相關細胞及組織產品在處理及使用過程中符合質量與安全規範。我們欣然通知，該指引的中文版本現已推出。詳情請參閱衛生署網站

https://www.advancedtherapyinfo.gov.hk/cbb/tc/doc/Guidance_for_Cell_and_Tissue_Products.pdf
或掃描下方二維碼以獲取《指引》的更多資訊。



衛生署署長

(黃頌欣醫生



代行)

2026 年 7 月 6 日

我們要建設一個健康的香港
並立志成為國際知名的公共衛生監管機構