

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, 17<sup>TH</sup> & 21<sup>ST</sup> FLOORS,  
213 QUEEN'S ROAD EAST,  
WANCHAI, HONG KONG

本署檔案 OUR REF: (94) in DHHQ/1010/7/2 Pt.3

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23 May 2022

Dear Doctor/ Dentist,

**Attention to Transplanting of Regulated Products  
under the Human Organ Transplant Ordinance (Cap. 465)**

We would like to draw your attention to the transplanting of regulated products under the Human Organ Transplant Ordinance (Cap. 465) (“the Ordinance”).

The Ordinance is to prohibit commercial dealings in human organs intended for transplanting, to restrict the transplanting of human organs between living persons and the transplanting of imported human organs, and for supplementary purposes connected with those matters. Part 7 (Section 7A to 7E) of the Ordinance provides that the Director of Health (“the Director”) may, on application, exempt certain commercial products made from human organs, i.e., regulated products, for transplant purposes from the application of the Ordinance, given that the product falls within the definition of regulated product and meets the criteria for exemption under the Ordinance.

Before using the regulated products for transplant purpose, registered medical practitioners and dentists need to ensure that the regulated products have been exempted by the Director. The medical practitioners and dentists are reminded to:

- check with the updated list of the exempted regulated products to ascertain whether the regulated products of interest have already been exempted;
- look for the exemption number issued by the Department of Health (“the DH”) on the outer package of the regulated products;
- keep a good utilisation record of the exempted regulated products to allow tracing individual recipients of a particular batch of the regulated products; and
- report any serious adverse event and serious adverse reaction to the DH.

As the approved regulated products are exempted from the application of Section 6 of

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the Ordinance (Information about transplant operations), for transplants using exempted regulated products, the medical practitioners do not need to supply to the Human Organ Transplant Board the information as specified in the prescribed Form 2 of the Human Organ Transplant Regulation (Cap. 465A). In addition, the medical practitioners and dentists do not need to submit the DH Return Form on the transplant of the exempted regulated products to the DH.

The list of the exempted regulated products as at 23 May 2022 is enclosed herewith for your reference. Information on the exemption of the regulated products under the Ordinance, including the updated list of the exempted regulated products, is available at [https://www.dh.gov.hk/english/useful/hot\\_exemption.html](https://www.dh.gov.hk/english/useful/hot_exemption.html) (accessible via the QR code below). Should you have any doubts on the exemption status of the regulated products or any other questions on the exemption of regulated products, please feel free to contact us at -

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Thank you for your attention.

Yours faithfully,

A handwritten signature in black ink, appearing to read 'Raymond Leung', positioned above the printed name.

(Dr Raymond LEUNG)  
for Director of Health

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