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25 June 2021

Chairlady
Hong Kong Medical and Healthcare Device Industries Association

Dear Chairlady,

Pharmacy and Poisons (Amendment) Ordinance 2020 to commence on 1 August 2021

We write to inform you that all provisions of the Pharmacy and Poisons (Amendment) Ordinance 2020 (“the Amendment Ordinance”) will come into operation on **1 August 2021**.

The Amendment Ordinance introduces a clear regulatory framework for Advanced Therapy Products (ATPs) which cover gene therapy products, somatic cell therapy products and tissue engineered products. After the Amendment Ordinance comes into operation, ATPs will form a specific subset of pharmaceutical products under the Pharmacy and Poisons Ordinance (Cap. 138). As such, requirements for pharmaceutical products under Cap.138 and other relevant ordinances will apply to ATPs. These include registration prior to marketing, obtaining prior approval for conducting clinical trials, licensing of manufacturers and distributors, and import/export control. Besides, there will be additional requirements on labelling and record keeping specific to ATPs to enhance traceability of the products.

To enable stakeholders to have better understanding of the enhanced regulatory framework for ATPs, the Pharmacy and Poisons Board of Hong Kong (“the Board”) and the Drug Office of the Department of Health (“DH”) have prepared guidance documents relevant to ATPs. In addition, the Board has published in the Gazette the following new edition of Codes of Practice (“COPs”) which will take effect on **1 August 2021**:

- Code of Practice for Holder of Wholesale Dealer Licence (2021);
- Code of Practice for Licensed Manufacturers and Registered Authorized Persons (2021);
- Code of Practice for Listed Seller of Poisons (2021); and
- Code of Practice for Authorized Seller of Poisons (2021).

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Regarding the Amendment Ordinance, regulatory information and guidance documents relating to ATPs, and new edition of COPs, please visit the dedicated website of the Drug Office of the DH (https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/atp_regulation.html) and the website of the Board (https://www.ppbhk.org.hk/eng/regulation_of_atp.html). You may also scan the QR codes printed at the end of the letter to access these websites.

Should you have any enquiries, please feel free to contact Dr. Daniel CHIK at 2961 8418 or Dr. Andrew CHOY at 2961 8537.

Yours faithfully,



(Tony CHAN)
for Director of Health



Dedicated Website of
Drug Office



Website of the Board