**Business Facilitation Advisory Committee**
**Wholesale and Retail Task Force**

***Implementation of the Code of Practice***
***for Holders of Wholesale Dealer Licence***
***under the Pharmacy and Poisons Ordinance Cap. 138***

## Purpose

This paper aims to brief members on the backgrounds and implementation of the Code of practice for holders of Wholesale Dealer Licence under the Pharmacy and Poisons Ordinance Cap. 138.

## Background

2. In late 2009, the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong made a total of 75 recommendations after reviewing the regulatory regime of pharmaceutical products.

3. One of these recommendations was to introduce a code of practice for wholesalers detailing their roles and responsibilities, including the requirement of batch release certificate, the reporting of adverse drug reactions, proper storage and transportation of drugs etc. In this connection, the Department of Health implemented the recommendation through the amendment to the Pharmacy and Poisons Ordinance, Cap 138.

4. The amendments to the Pharmacy and Poisons Ordinance took effect on 6 February 2015 and, among others, a new section 4B was added to the Pharmacy and Poisons Ordinance to empower the Pharmacy and Poisons Board ("the Board") to issue codes of practice for providing practical guidance to licensed traders including holders of wholesale dealer licence. The Pharmacy and Poisons Regulations provides that non-compliance with such code may lead to disciplinary actions.

5. Subsequently, the Code of practice for holders of Wholesale Dealer Licence ("the Code"), which was drafted in consultation with the trade and relevant stakeholders, was endorsed by the Board and came into force on 1 October 2015.

6. The Code provides guidance on the roles and responsibilities of the holders Wholesale Dealer Licence ("WDL") and sets out the minimum standards concerning the distribution of pharmaceutical products. Distribution includes procuring, purchasing, holding, storing, selling, supplying, importing, exporting, and the delivery of pharmaceutical products from the premises of a WDL holder to other premises. Contravention of the Code may lead to revocation or suspension of the WDL for such period as the Pharmacy and Poisons (Wholesale Licences) Committee of the Board thinks fit.

**Progress of the implementation of Code of Practice**

7. The Drug Office of the Department of Health ("DH"), the executive arm of the Board, assisted in the implemention of the Code. To facilitate holders of WDL to comply with the requirements, the DH organized 11 briefing sessions in 2014 and 2015. Furthermore, DH pharmacists review the compliance with the Code during inspections conducted at the premises of these WDL holders.

8. The implementation progress has been reviewed in 2016 and it was noted that the general compliance of holders of WDL was satisfactory. The most common areas that may need improvement were documentation and working procedures. The DH will organize two briefing sessions (one in May and one in June 2017) for holders of WDL to discuss the above observations found during inspections in 2016 for enhanced compliance.

**Way Forward**

9. Members are invited to note the content of this paper.

Department of Health
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