Annex E

Recommendations Requiring Legislative Amendments

The implementation of some recommendations of the Review Committee requires amendments to the existing Pharmacy and Poisons Ordinance (Cap 138). This Annex sets out the legislative amendments required.

2. We will work with the Department of Justice (DoJ) to prepare the legislative amendments. The trade and other stakeholders will be consulted before the legislative proposals are submitted to the Legislative Council.

Regulation of Wholesalers

(a) **Requiring wholesalers handling non-poisons to apply for a licence:** At present, wholesalers of drugs which are non-poisons (e.g. vitamins) are not subject to licensing control. The Review Committee considers that patients' health would be affected if these drugs are not handled properly. The Review Committee recommends that the Department of Health (DH) require all wholesalers of non-poisons to apply for a licence so that DH could impose licensing requirements on them. Cap 138 will have to be amended to introduce the licensing requirements.

(b) **Requiring wholesalers to keep transaction records for Part II Poisons and non-poisons**: At present the law only requires wholesaler to keep transaction records for Part I Poisons. The Review Committee recommends that wholesalers also keep transaction records for all pharmaceutical products, including Part II Poisons and non-poisons. Cap 138 will have to be amended to introduce this requirement.

(c) **Introduction of a Code of Practice for wholesalers**: At present there are no guidelines governing the roles and responsibilities of

wholesalers on product quality, as opposed to the Good Manufacturing Practices (GMP) compliance for manufacturers. The Review Committee recommends that a Code of Practice be introduced for wholesalers. Cap 138 will be amended to stipulate that wholesalers will have to follow the Code of Practice when applying for a licence from DH.

Regulation of Importers and Exporters

(d) **Introduction of a Code of Practice for importers and exporters**: As in the case of wholesalers, at present there are no guidelines governing the roles and responsibilities of importers and exporters on product quality. The Review Committee recommends that a Code of Practice be introduced for importers and exporters. Cap 138 will be amended to stipulate that importers and exporters will have to follow the Code of Practice when applying for a licence from DH.

Regulation of Retailers

(e) **Requiring retailers handling non-poisons to apply for a licence**: At present, retailers of non-poisons are not required to apply for a licence. Although non-poisons are drugs of lower risk, they will still affect public health if not being handled properly. The Review Committee recommends that retailers selling non-poisons be required to apply for a licence from DH. Cap 138 will be amended to introduce the licensing requirement.

(f) **Providing legal status for the Code of Practice for Authorized Sellers of Poisons (ASPs) and introducing a Code of Practice for Listed Seller of Poisons (LSPs)**: The Code of Practice for ASPs has no legal status at present, and there is no Code of Practice for LSPs to follow with regard to the handling of drugs. The Review Committee recommends that a provision in Cap 138 be added to stipulate that both ASPs and LSPs have to follow their respective Code of Practice.

(g) **Requiring the presence of pharmacists during all business hours of pharmacies**: At present, Cap 138 requires a registered pharmacist to be present in an ASP for not less than two-third of its opening hours. The Review Committee recommends that a registered pharmacist be present whenever an ASP is open for business. This will improve the professional services provided by pharmacists to the public. Cap 138 will need to be amended to this effect.

(h) **Requiring Part I Poisons be stored in locked receptacles**: At present only Part I Poisons in the First and Third Schedules of Cap 138 are required to be stored in a locked receptacle. The Review Committee recommends that all Part I Poisons have to be stored in locked receptacle to ensure that the pharmacist has complete control over the sale of Part I Poisons. Cap 138 has to be amended to this effect.

(i) **Empowering the Pharmacy and Poisons Board (PPB) to revoke licences of ASPs**: At present the PPB can only stop renewing licences of ASPs at the beginning of each year, but has no authority to revoke the licence during the year. The Review Committee recommends giving such authority to the PPB so that the licence of the ASP can be revoked if it has committed a serious offence.

Pre-market control of drugs

(j) **Changing the term "Poison 毒藥" on drug labels**: The term "poison" in drug labels arouses unnecessary concern of the public regarding the safety of the drug. The Review Committee recommends DH and the PPB consider other alternative terms. The term is currently specified in the law and therefore legislative amendment is required.

(k) **Delection of the phrase "to be marketed for use within Hong Kong" on the certificate of registration of pharmaceutical**

products: DH issue the certificate of registration based on the quality, efficacy and safety of drugs, having no regard to whether the product infringes any intellectual property rights (IPR). The Review Committee recommends deleting the phrase "to be marketed for use within Hong Kong" as DH is not in a position to confirm whether the drug can be sold in the market from the angle of IPR. As the phrase is stipulated in the law, legislative amendment is required.

(l) **Extending the validity of clinical trial certificate from not more than 2 years to not more than 5 years**: It is now stipulated in the law that the validity of clinical trial certificate is not more 2 years. The Review Committee recommends amending the law to extend the period to not more than 5 years so that many clinical trials lasting more than 2 years can continue without the need to apply again for a certificate.

Penalty

(m) **Requiring the convicted person to bear the costs for analyzing exhibits in court cases**: The cost for analyzing exhibits in court cases could be substantial. The Review Committee recommends that the law be amended to require the convicted person to bear such costs in order to increase the deterrent effect.