CHAPTER 5 REGULATION OF IMPORTERS/EXPORTERS, WHOLESALERS AND RETAILERS

Overview

5.1 This chapter provides an overview of the existing regulatory regime for the other three levels of players in the drug supply chain, viz. importers/exporters, wholesalers, and retailers; and presents the Review Committee's findings and recommendations on areas for improvement.

Importers/Exporters, Wholesalers and Retailers

5.2 As provided in the Pharmacy and Poisons Ordinance (the Ordinance), importers/exporters and wholesalers can only resell drugs to retailers, hospitals, clinics and other authorized persons, while retailers can sell drugs direct to members of the public. Depending on the types of drugs being handled, these two levels of traders are issued with different kinds of licences.

Existing Regulatory Regime for Importers/Exporters and Wholesalers

5.3 There are around 240 importers/exporters licensed to deal with the import/export of pharmaceutical products not classified as poisons, and 860 wholesalers licensed to deal with import/export, and wholesale within Hong Kong, of all pharmaceutical products whether or not classified as poisons.

Types of Licences for Importers/Exporters and Wholesalers

5.4 Under section 28A of the Ordinance, for a company importing or exporting drugs not classified as poisons into or out of Hong Kong, a Certificate of Registration as an Importer and Exporter (IE) is required.

5.5 Under regulation 26 of the Pharmacy and Poisons Regulations, for a company handling import and export and/or wholesaling in drugs classified as poisons under the Ordinance, a Wholesale Poisons Licence (WPL) is required.

5.6 In addition, holders of either IE or WPL importing or exporting drugs of any classification must also obtain beforehand an Import Licence (IL) or Export Licence (EL) for each consignment as appropriate under the Import and Export (General) Regulations. While the licensing authority for ILs and ELs is vested in the Director-General of Trade and Industry (DGTI), the DGTI has delegated

the power for issue of ILs and ELs in relation to drugs to DH. In practice, DH will only issue ILs and ELs for either registered drugs or unregistered drugs imported for re-export purpose only.

5.7 No licence is required for a company trading in drugs of non-poisons inside Hong Kong, provided that the drugs are registered.

5.8 To summarize, the licensing requirements for traders are as follows –

Traders	Licence required
Wholesalers of poisons	WPL
Importers and exporters of poisons	WPL
Wholesalers of non-poisons	Nil
Importers and exporters of non-poisons	IE
Importers and Exporters of all pharmaceutical products	IL or EL for each consignment

Processing of Licence Applications

5.9 IE and WPL are issued by the Wholesale Licences and Registration of Importers & Exporters Committee (IE Committee) under the Pharmacy and Poisons Board. General licensing conditions include suitable premises and adequate knowledge of the person-in-charge in the pharmaceutical trade.

5.10 Any company can apply for an IE or WPL. Upon receipt of an application, DH inspector will conduct an unannounced pre-licensing inspection at the premises for the purposes of assessing the suitability of premises for the storage of drugs to be handled and conducting interview with the person-in-charge of the proposed pharmaceutical business regarding his knowledge and experience in the pharmaceutical trade. After an applicant has satisfied the licensing conditions, the application will be referred to the IE Committee for decision, which may also impose additional conditions, such as restricting the applicant to deal with drugs mentioned in the application form only. An IE or WPL is valid for not more than one year and is renewable annually.

Licensing Requirements

5.11 Wholesalers are required to keep proper records of all transactions involving Part I poisons in the format specified in the Ordinance, including the name of the drug, date of transaction, to whom the drug is sold, quantity, etc. The objective is to ensure that the drugs are sold to persons authorized to handle them and to ensure traceability of drugs in case of product recall. Every

transaction must be supported by the relevant documents signed by the purchaser. The record and the signed documents must be kept for two years.

5.12 In addition, wholesalers are required to devise and maintain a recall mechanism so as to ensure comprehensive and speedy recall of their products at various levels whenever required. The recall mechanism is a key area for consideration when relevant licences are renewed. To facilitate wholesalers in devising their own recall mechanism, DH has issued a set of recall guidelines since 2000.

Monitoring and Inspections

5.13 Importers/exporters and wholesalers are monitored by DH by means of unannounced inspections. Each licensed premises is inspected about once a year on average. During inspections, transaction records with the relevant supporting documents, storage conditions of the premises, and the labelling of the pharmaceutical products are audited. If non-compliance with the law is found, prosecution action will be initiated. Convicted persons are liable to a maximum penalty of $100,000 fine and two years' imprisonment. The Committee may also issue a warning letter, revoke or suspend the licence for such period as it thinks fit after the licensee has been convicted of an offence. For failure to comply with the licensing requirements, the dealers will be instructed to rectify the situation.

5.14 Import and export control of drugs is conducted by staff of the Customs and Excise Department (C&ED) at various control points to ensure all pharmaceutical products have the required IL or EL. C&ED also conducts post-shipment consignment checks on a specified number of licences referred weekly by DH. The current weekly quota is 18 as agreed between C&ED and DH, in consideration of the staff resources of C&ED deployed for such purpose.

5.15 DH has adopted a risk-based approach towards import and export control of drugs. For Part I Poisons and antibiotics, importers/exporters and wholesalers are required by the Ordinance to keep records of all transactions (purchasing and supplying) with supporting documents. DH inspectors will cross check with the ILs and ELs and examine the records and supporting documents of these high risk pharmaceutical products during inspections of importers/exporters and wholesalers to detect any local sale of unregistered Part I poisons or antibiotics. For lower risk drugs classified as Part II poisons and non-poisons such as vitamins and medicated shampoos, DH has implemented market surveillance to detect any unregistered drugs being offered for sale in the local market.

Findings and Recommendations

5.16 The Review Committee identifies a number of areas for improvement in the existing regulatory regime for importers/exporters and wholesalers, and the recommendations are set out in the following paragraphs.

Licensing on Wholesalers of Non-poisons

5.17 The Review Committee notes that wholesalers of drugs which are non-poisons (e.g. stomach antacids, paracetamol and multivitamins) are not subject to inspection and licensing control at present. As a result, wholesaler may not maintain an accurate record on the transaction of these non-poisons. The Review Committee considers this situation undesirable, as non-poisons, though less dangerous, could also endanger patient health if they are not stored and handled properly. It is essential to monitor their quality and maintain a complete record to facilitate recall, if necessary. Moreover, wholesalers of non-poisons usually handle drugs in large quantity and are therefore an important link in the supply chain and an important player of drug quality maintenance.

5.18 The Review Committee **recommends** that DH requires all wholesalers of non-poisons be subject to inspection and licensing control. Although non-poisons are of lower risk, it is still important that wholesalers who handle them have the required storage facilities to protect drug quality, and that they maintain complete transaction records to facilitate recalls when necessary.

Keeping of Transaction Records

5.19 The Review Committee notes that existing record-keeping requirements under the law apply to transactions of Part I poisons only. There are no such requirements for Part II poisons or non-poisons, thus creating difficulties in the event of a drug recall. In addition, the existing transaction record form does not contain information such as registered pack size and batch number which is useful for monitoring and recall purposes.

5.20 The Review Committee **recommends** that DH requires all wholesalers to keep transactions records of all pharmaceutical products, including Part II poisons and non-poisons in the same manner as for Part I poisons. DH should take the opportunity to review the transaction record form with a view to providing more comprehensive information on the quality and whereabouts of the drugs concerned. The Review Committee further **recommends** that DH requires wholesalers to keep samples of each batch of drugs handled to facilitate investigation when needed.

Secondary Packaging of Pharmaceutical Products

5.21 The Review Committee finds that importers/exporters and wholesalers are currently permitted to perform secondary packaging of pharmaceutical products (i.e. packaging activities which do not expose the drug to air such as putting bottles of drugs into carton boxes, putting strip-packed tablets into carton boxes, labelling of bottles or carton boxes, etc.). The Review Committee considers this situation undesirable as problems such as wrong labelling or wrong content of carton boxes may arise in the secondary packaging process. As a matter of fact, some of the drug incidents occurred in early 2009 were caused by wrong packaging.

5.22 The Review Committee **recommends** that primary and secondary packaging should only be carried out by a licensed manufacturer who complies with the GMP requirements. A new category of secondary packaging licence will be introduced for such purpose. The Review Committee is aware of the impact of the recommendation on the business operation of importers/exporters and wholesalers, and suggests that an appropriate transition period be provided to help importers/exporters and wholesalers prepare for the change.

Introduction of a Code of Practice

5.23 The Review Committee finds that at present there are no guidelines governing the roles and responsibilities of importers/exporters and wholesalers on product quality, as compared with GMP for compliance by manufacturers. For instance, importers/exporters and wholesalers are not required to obtain from their overseas suppliers relevant quality control documents, such as batch release certificates, to ascertain product quality. Besides, there is no guidance for them to report adverse drug reactions of their imported drugs to DH. The Review Committee considers this situation unsatisfactory, as import of substandard drugs or poor handling of drugs by importers/exporters and wholesalers will affect public health. It is also unfair to local manufacturers who have to follow GMP requirements in respect of product manufacturing and quality control.

5.24 The Review Committee **recommends** that DH introduces a code of practice for importers/exporters and wholesalers detailing their roles and responsibilities, including the requirement of batch release certificate, the reporting of adverse drug reactions, points to note in storage and transportation of drugs, etc. DH should draft such a code of practice in consultation with DoJ and the wholesale industry, and include the code of practice in the licensing conditions for importers/exporters and wholesalers, so that sanctions could be imposed by the Pharmacy and Poisons Board for any non-compliance with the

code of practice. DH should also organize briefing sessions to help staff of importers/exporters and wholesalers familiarize with the content of the code of practice.

Inspections and Enforcement

5.25 The Review Committee finds the current inspection frequency of once a year on average to premises of importers/exporters and wholesalers insufficient, taking into account the large volume of drug items handled by importers/exporters and wholesalers and their risk to public health.

5.26 The Review Committee **recommends** that DH strengthens the monitoring of importers/exporters and wholesalers by means of more frequent and more detailed inspections, especially after the introduction of a code of practice. DH should review the existing inspection guidelines and checklists to enhance the quality of inspections.

Checking of Pharmaceutical Products at Ports of Entry

5.27 At present, pharmaceutical products entering into Hong Kong are checked by the Customs and Excise Department (C&ED) at various ports of entry. C&ED has to contact DH if they have any doubts about a particular consignment as they do not possess expertise about pharmaceutical products. The Review Committee notes that there is no dedicated DH team on the spot to check the imported products, which undermines the effectiveness of dealing with problematic pharmaceutical products when they arrive at Hong Kong.

5.28 The Review Committee **recommends** that DH sets up a dedicated team of pharmacist inspectors to advise C&ED on pharmaceutical imports at various ports of entry, such as whether the imported products require registration, or whether the imported products fit the description in the import licence.

Import and Export Control of Drugs

5.29 The Review Committee notes that there is at present no record and tracking system in place to trace if drugs imported into Hong Kong for re-export purpose are indeed exported, thus creating a loophole for the illegal sale of imported unregistered drugs in local market. The Review Committee **recommends** that DH sets up a record and tracking system as a matter of priority. When pharmaceutical products are imported for re-export purposes, DH would record the name and amount of the products. When the products are due for re-export, DH would check the information against the import licence to ensure that all the products are re-exported without being sold in Hong Kong.

5.30 The Review Committee further **recommends** that DH prescribes in the licensing conditions for ILs for the products for re-export that the importer should not sell unregistered imported drugs in Hong Kong and must re-export the products within a specified period of time, say one year.

5.31 The Review Committee acknowledges that the weekly quota of 18 for post-shipment consignment checks of licences is agreed between C&ED and DH in consideration of the workload of C&ED staff. Nevertheless, the Review Committee notes that this weekly quota has remained unchanged for many years while the numbers of ILs and ELs have been on an increasing trend in recent years. The Review Committee **recommends** that DH conducts joint review with C&ED to determine a new weekly quota which represents a statistically significant sample size of the ILs and ELs population.

5.32 The Review Committee notes that many drug exporters choose to export the products by mail. The daily average of such mail parcels of drugs is around 700. The Review Committee considers that the monitoring of export of drugs by mail should be stepped up and **recommends** that DH requires exporters who chose to export products by mail to clear their products at designated post offices where C&ED staff are present. DH will include the requirement in the ELs. DH will also discuss with C&ED and Post Office on the implementation arrangements.

5.33 The Review Committee also notes that there is no electronic record system among DH, C&ED and TID to facilitate the tracking of imported and exported drugs. The Review Committee **recommends** that DH develops an electronic record system to facilitate the tracing and tracking of imported unregistered drugs intended for re-export.

Existing Regulatory Regime for Retailers

5.34 There are a total of around 3,800 retailers, including 500 authorized sellers of poisons and 3,300 listed sellers of poisons. They are licensed to deal with retail business of drugs.

Types of Licences for Retailers

5.35 "Authorized Sellers of Poisons" (ASPs), commonly known as "dispensaries" or "pharmacies" (藥房), are authorized to sell Part I Poisons, Part II Poisons and non-poisons. The Ordinance requires that registered pharmacists should be present at the premises of ASPs to supervise the sale of poisons. The

name, certificate of registration and working hours of the pharmacist must be displayed in a conspicuous location inside the ASP. Besides, sale of First Schedule Part I Poisons should be recorded and kept in a "poisons book", while doctor prescription is required for sale of Third Schedule Part I Poisons. Both the sales record in the "poisons book' and the doctor prescription records have to be kept for two years and are subject to DH inspection. Furthermore, First and Third Schedules Part I Poisons must be stored in a locked receptacle away from customers' access within the ASP premises.

5.36 "Listed Sellers of Poisons" (LSPs), commonly known as "medicine companies" (藥行), are only allowed to sell Part II Poisons and non-poisons only. Moreover, they do not have the service of a registered pharmacist.

Licensing Requirements for ASPs

5.37 Under the Ordinance, the Pharmacy and Poisons Board will issue an ASP licence if it is satisfied that the applicant is a fit and proper person and the premises is suitable to conduct the retail sale of poisons. In addition, the premises have to be under the personal control of a registered pharmacist, which is defined as being present for not less than two-third of the opening hours of the premises.

5.38 Apart from the legal requirements, ASPs should comply with the "Code of Practice for Authorized Sellers of Poisons" and "Guidelines on the Labelling of Dispensed Medicines" promulgated by the Pharmacy and Poisons Board.

Processing of ASP Applications

5.39 Upon receipt of an ASP application, DH inspector will search the Company Registry for company profile of the applicant and interview the owner or person in charge of the applicant company as well as the registered pharmacist to ascertain if they have sufficient knowledge and experience and are "fit and proper" to conduct the retail sale of poisons. One or more unannounced on-site inspections will then be conducted for the purposes of assessing the suitability of the premises. Furthermore, DH inspector will conduct a criminal record search of all persons involved in the daily operation of business. The Board will refuse the application if any of the persons involved has had two convictions in the past three years related to any specified drug offences.

5.40 ASP licences are valid till the end of each year. At the beginning of each year, the Pharmacy and Poisons Board may renew the certificates upon application. In considering the renewal applications, the Board will assess if

any person involved in the daily operations of the ASP has had two convictions in the past three years in the same manner as in the assessment of a new applications.

Licensing Requirements for LSPs

5.41 The licensing requirements of LSPs are similar to that of ASPs, which include the suitability of the premises for the sale of pharmaceutical products and the fitness and properness of the persons involved in the business operation.

5.42 Unlike ASPs who can purchase pharmaceutical products in bulk packs and dispense to customers, LSPs cannot dispense prescriptions. LSPs must sell pharmaceutical products in their original packages as received from suppliers.

Processing of LSP Applications

5.43 The Pharmacy and Poisons (Listed Sellers of Poisons) Committee of the Pharmacy and Poisons Board (LSP Committee) is responsible for the licensing of LSPs. Upon receipt of an LSP application, DH inspector will make an unannounced inspection at the premises of the applicant for the purpose of assessing the suitability of the premises and interviewing the persons involved in the daily business operation to ascertain if they are "fit and proper" to conduct the retail sale of Part II Poisons and non-poisons.

5.44 The inspection report will be submitted to the LSP Committee for consideration. The LSP Committee will refuse the application if any person involved in the daily business operation has had two or more convictions over the past three years, or one conviction over the past three years related to specified drug offences.

5.45 Same as ASP licences, LSP licences are valid till the end of each year and the LSP Committee may renew the certificates upon application at the beginning of each year. In considering the renewal applications, the LSP Committee will assess if any person involved in the daily operations of the LSP has had two convictions in the past three years or one conviction over the past three years related to specified drug offences in the same manner as in the assessment of a new application.

Monitoring of ASPs and LSPs

5.46 ASPs and LSPs are monitored by means of unannounced inspections by DH inspectors, test-purchases to detect any incidents of illegal sale of medicines, and prosecution of offenders. During an inspection, issues related to the

licensing conditions of the particular licensee and compliance with the statutory requirements will be audited. If the retailer is found to have breached a licensing condition, the case will be referred to the Pharmacy and Poisons Board for consideration. If non-compliance with the law is found, either during an inspection or during a test-purchase, prosecution action will be initiated. Convicted persons are liable to a maximum penalty of a $100,000 fine and two years' imprisonment. Following a conviction, further actions will be taken by the Disciplinary Committee of the Pharmacy and Poisons Board. The outcome may be the issue of a warning letter against the retailers concerned, or suspension of the licence for a period of time.

5.47 Inspections are conducted about twice a year per premises on average, with a higher frequency for retailers with a poor track record of law compliance.

Findings and Recommendations

5.48 The Review Committee identifies a number of areas for improvement in the existing regulatory regime for retailers, and makes the recommendations as set out in the following paragraphs.

Regulation of Retailers of Non-poisons

5.49 The Review Committee notes that retailers of pharmaceutical products classified as "non-poisons" are not subject to any licensing control. Consequently, there are no means to know their exact number and whereabouts. While the Review Committee acknowledges that non-poisons are drugs of lower risk, they will still pose risk to public health if they are not handled properly.

5.50 The Review Committee **recommends** that retailers of non-poisons also be subject to DH licensing and inspection control. The licensing requirements should be similar to that of LSPs while the licence period may be longer and the DH inspection may be less frequent in view of the lower risk of non-poisons to public health as compared with LSPs.

Duration of Presence of Pharmacist in ASPs

5.51 The Review Committee notes that the Ordinance only requires a registered pharmacist to be present in an ASP for not less than two-third of its opening hours. This means that for the remaining one-third opening hours, members of the public cannot have access to the professional services of

pharmacist. It also weakens the pharmacist's supervision over the sale of Part I Poisons at ASP.

5.52 The Review Committee **recommends** DH amends the Ordinance to the effect that a registered pharmacist should be present in an ASP whenever it is open for business. This will improve the professional services provided by pharmacists at ASPs (i.e. community pharmacists). The Review Committee, however, acknowledges that the implementation of this recommendation requires consideration of the market operating conditions and availability of sufficient pharmacists. The Review Committee urges DH to set a clear policy direction in this regard and draw up an implementation timetable. DH should liaise with the University Grants Committee with a view to offering more places in the pharmacy programmes of universities.

5.53 To enhance the role of pharmacists in the control of the storage and supply of drugs at ASPs, the Review Committee further **recommends** that heightened enforcement actions be taken against those non-pharmacists who violate and interrupt the pharmacists' performance of their duties at ASPs.

5.54 One Member of the Review Committee proposes and another Member supports a proposal that ASPs should either be fully owned or majority owned by pharmacist who should hold a minimum of 51% share of an ASP. After very thorough discussion, the majority of the Members of the Review Committee consider that this proposal is not immediately workable and that the views of the owners and operators of ASPs should also be taken into account. Furthermore, this proposal will have implications in relation to the anti-competition law being introduced. Other than these two members, the rest of the Review Committee members do not support this proposal.

Storage of Part I Poisons at ASP Premises

5.55 The Review Committee notes that while all Part I Poisons have to be sold under the supervision of pharmacists at ASPs according to the Ordinance, only First and Third Schedules Part I Poisons are required to be stored in a locked receptacle. Other Part I Poisons can be stored in any part of the premises. This provides an opportunity for these poisons to be sold to customers by other staff when the pharmacist is not present.

5.56 The Review Committee **recommends** that DH requires all Part I Poisons be stored in locked receptacle in the premises of an ASP and that only the pharmacist should hold the key to the locked receptacle in order to ensure that the pharmacist has complete control over the sale of Part I Poisons in the premises of an ASP.

Code of Practice

5.57 The Review Committee notes that the code of practice for ASPs has no legal status at present. The Review Committee also notes that there is no code of practice for LSPs and thus are no guidelines for staff at LSPs to follow in storage and handling of drugs.

5.58 The Review Committee **recommends** that a provision in the Pharmacy and Poisons Ordinance be added for the issuance and revision of the code of practice for ASPs to give a legal status to the code to enhance monitoring on the operation of ASPs. The Review Committee also **recommends** that DH drafts a code of practice to provide detailed guidance for staff at LSPs in storage and handling of drugs. The code of practice for LSPs should also enjoy the same legal status as ASPs.

Revocation of Licences for ASPs

5.59 The Review Committee notes that at present the Pharmacy and Poisons Board can renew the licences for ASP at the beginning of each year. However, the Pharmacy and Poisons Board has no authority to revoke the licence of an ASP when the ASP concerned has committed a serious drug offence. The Board can only revoke the ASP licence for a certain period of time or do not renew its licence upon expiry in extreme situation.

5.60 The Review Committee **recommends** giving the Pharmacy and Poisons Board the authority to revoke the licence of an ASP at any time. However, before making such a decision, the Pharmacy and Poisons Board should provide an opportunity for the ASP concerned to make representations to defend itself.

Convictions affecting Applications for Issue and Renewal of ASP and LSP licences

5.61 The Review Committee notes that the Pharmacy and Poisons Board would refuse an ASP or LSP application if any person involved in the daily business operation has had two convictions in the past three years related to the sale of any drug of abuse, the possession or sale of any counterfeit drugs, or the possession or sale of any unregistered pharmaceutical products. However, the sale of Third Schedule Part I Poisons without doctor prescription which is the most common misconduct of ASPs is not taken into account. The Review Committee also considers that other types of convictions of the licensees should be taken into account when considering the issuance and renewal of ASP and LSP licences.

5.62 The Review Committee **recommends** that the sale of Third Schedule Part I Poisons without doctor prescription be considered as a conviction record for the refusal of ASP or LSP applications. DH should also evaluate what other drug offences should be included based on their public health impact.

Inspections and Enforcement

5.63 The Review Committee finds the current inspection frequency of twice a year on average to premises of ASPs and LSPs insufficient, as they provide drugs direct to the customers and mal-practices of some ASPs are often found.

5.64 The Review Committee **recommends** that DH strengthens the monitoring of ASPs and LSPs by means of more frequent and more detailed inspections.

Purchase of Drugs from Licensed Traders only

5.65 The Review Committee notes that there is at present no requirement for wholesalers of "non-poisons" to have licence. In this connection, during DH inspections, it was often found that some drugs, in particular those "non-poisons", being sold at ASPs are of unknown origin. The quality of these drugs is in doubt because it is uncertain whether the quality, means of transportation and storage conditions are appropriate for the drugs concerned. Moreover, as the source of these drugs is unknown, difficulties will arise in the event of drug recall.

5.66 The Review Committee **recommends** that DH requires ASPs and LSPs to purchase drugs from licensed traders only after the recommendation in paragraph 5.18 above that wholesalers of non-poisons be subject to inspection and licensing control has been implemented. This is to ensure product quality and to facilitate product recall if necessary.

Written Orders of Drugs by ASPs, LSPs and Private Doctors

5.67 The Review Committee notes that there is at present no requirement for ASPs or LSPs to place orders for drugs in writing only. The same also applies to private doctors, even though it is stated as a recommended practice in the "Good Dispensing Practice Manual" published by the Hong Kong Medical Association.

5.68 The Review Committee agrees that written drug orders serve two major purposes. First, it contributes to building up a complete set of record in the drug

supply chain all the way from the primary source to the patients. It thus facilitates the tracing of source of drugs in the event of drug recall. It also deters the sale of unregistered drugs and purchase of drugs from unregistered traders as these unlawful acts do not have the support of written orders.

5.69 Second, it facilitates ASPs, LSPs and private doctors to verify if the drugs delivered are actually the drugs ordered. Since there is always a time gap between the ordering and delivery of drugs, a written drug order can assist the receiving staff, who may not be the ordering staff, to verify if the correct drugs are delivered. Furthermore, verbal order for drugs is prone to errors, as many drug names are similar and misunderstanding will easily arise.

5.70 The Review Committee acknowledges the concerns and difficulties of ASPs and some private doctors in complying with the written drug order requirement. In particular, for ASPs who may have to place over 100 drug orders daily, the amount of manpower and efforts involved may be quite significant, while many ASPs only have a few staff members and a limited storage area for the written records.

5.71 The Review Committee considers that protection of public health is of the top priority. Placing drug orders in writing contributes to building up a complete set of drug movement record, reducing errors in drug delivery and receipt, and combating illegal sale of drugs. The Review Committee also considers that ASPs and private doctors should not have great difficulties to comply with the requirement. The Review Committee suggests manufacturers and wholesalers design a standard procurement form for use by their clients in order to save their efforts. In fact, many advanced countries, for example in Europe, are already following this practice which has proved to be very convenient and easy to use.

5.72 In the light of the above considerations, the Review Committee recommends that all orders for drugs should have written records. DH should include this requirement in the licensing conditions for ASPs and LSPs, and in parallel, add in the licensing conditions of manufacturers and wholesalers that they can only supply drugs to ASPs, LSPs and private doctors with the support of written orders. The Review Committee is also pleased to note that the Hong Kong Medical Association and the Pharmaceutical Distributors Association of Hong Kong are supportive of this recommendation. Furthermore, it is noted that the written order practice is already recommended in the "Good Dispensing Practice Manual" issued by the Hong Kong Medical Association which should be observed by all doctors as advised by the Hong Kong Medical Council.

5.73 The Review Committee notes the objection of Hong Kong Doctors Union to the mandatory requirement of written order for drugs which is only supported by one other member. The rest of the other members support this recommendation.

Sale of Pharmaceutical Products in Original Packing by ASPs

5.74 The Review Committee notes that ASPs are currently permitted to purchase pharmaceutical products in bulk packs and then repack them into smaller packs for the purpose of dispensing them to customers. However, this "repacking" process could pose risk of contamination or mix-up of drugs, thus endangering public health.

5.75 The Review Committee **recommends** that ASPs only sell pharmaceutical products in their original packing to avoid human errors in the repacking process, save in the case of a doctor prescription drug which is required by law to be dispensed in exact quantity in accordance with the prescription and in the case of pharmacist dispensing drugs to patients according to their need with proper labelling. This recommendation is also in line with the worldwide trend of increasing use of drugs in their original packing. The Review Committee, however, understands that the manufacturers and wholesalers need time to adjust the pack sizes of their products to meet market demand. The Review Committee suggests DH draw up an implementation timetable for the recommendation with an appropriate transition period in consultation with the manufacturing and wholesale industry.

Keeping of Transaction Records

5.76 The Review Committee notes that there is no requirement at present for ASPs and LSPs to keep record of every transaction involving pharmaceutical products. This hinders the tracing of source of drugs in the event of drug recall.

5.77 The Review Committee **recommends** that DH requires ASPs and LSPs to keep all the supporting documents including drug orders and sales invoices related to every purchase of all pharmaceutical products, and the documents should be kept as long as the expiry date of the pharmaceutical product concerned for DH inspection if necessary. DH should add this requirement as a licensing condition.