

## **CHAPTER 5**

**Department of Health  
Food and Health Bureau**

**Control of western medicines**

**Audit Commission  
Hong Kong  
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*This audit review was carried out under a set of guidelines tabled in the Provisional Legislative Council by the Chairman of the Public Accounts Committee on 11 February 1998. The guidelines were agreed between the Public Accounts Committee and the Director of Audit and accepted by the Government of the Hong Kong Special Administrative Region.*

Report No. 53 of the Director of Audit contains 11 Chapters which are available on our website at <http://www.aud.gov.hk>.

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# CONTROL OF WESTERN MEDICINES

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## **PART 1: INTRODUCTION**

1.1 This PART describes the background to the audit and outlines the audit objectives and scope.

### **Importance of medicine regulation**

1.2 The **Department of Health (DH)** is responsible for overseeing the safety, efficacy and quality of medicines that are marketed in Hong Kong, irrespective of whether they are locally manufactured or imported. If medicines are not properly regulated, Hong Kong people could be exposed to potential health and safety risks.

### **Regulation of medicines**

1.3 Medicines include western medicines and Chinese medicines, which are regulated by different Ordinances. Regulation of western medicines in Hong Kong is essentially governed by the **Pharmacy and Poisons Ordinance (PPO — Cap. 138)**, whereas regulation of Chinese medicines is governed by the Chinese Medicine Ordinance (CMO, Cap. 549 — Note 1). This audit review mainly covers the control of western medicines. In parallel with this review, Audit has conducted a review of the control of Chinese medicines and undesirable medical advertisements. The audit findings are contained in a separate report (see Chapter 4 of the Director of Audit's Report No. 53).

1.4 As at 31 March 2009, there were some 19,500 western medicines (medicines — Note 2) registered in Hong Kong, with 70% imported and 30% manufactured locally. Medicines can be classified as poisons (Part I or Part II), non-poisons, dangerous drugs (DDs) and antibiotics. The medicines control framework in Hong Kong is risk-based. In the order of risk to public health, DDs are accorded the strictest control, followed by Part I

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**Note 1:** *The CMO regulates two categories of Chinese medicines, namely Chinese herbal medicines and proprietary Chinese medicines.*

**Note 2:** *“Medicine” and “pharmaceutical product” used in the PPO mean any substance or mixture of substances manufactured, sold, supplied or offered for sale or supply for use in human beings or in animals for:*

- (a) *the diagnosis, treatment, mitigation, alleviation or prevention of disease or any symptom thereof;*
- (b) *the diagnosis, treatment, mitigation, alleviation of any abnormal physical or physiological state or any symptom thereof; or*
- (c) *altering, modifying, correcting or restoring any organic function.*

poisons. Part II poisons and non-poisons are accorded a lower level of control. Appendix A provides a summary of the key controls over poisons, DDs and antibiotics at the retail level.

1.5 The PPO provides for the regulation of medicines in Hong Kong through control of the trade and medicines. Section 3 of the PPO also provides for the establishment of a **Pharmacy and Poisons Board (Board)**, with the Director of Health as the Chairman and comprising members from the pharmaceutical, medical and academic sectors (the Board structure is at Appendix B). Section 4A of the PPO further allows the Board to establish executive committees to register medicines and license medicine dealers.

1.6 The **Dangerous Drugs Ordinance (DDO — Cap. 134)** provides for the classification of a wide range of medicines as DDs, the sale and supply of which are subject to stringent controls due to their abuse potential. The **Antibiotics Ordinance (ABO — Cap. 137)** provides for the exercise of controls over the sale and supply of antibiotics.

### Control of the pharmaceutical trade

1.7 Dealers in the medicine supply chain (dealers) are subject to licensing control. They are:

- (a) manufacturers;
- (b) wholesalers of poisons (wholesalers);
- (c) importers/exporters (I/Es); and
- (d) retailers of poisons (retailers) who are classified into authorised sellers of poisons (ASPs) and listed sellers of poisons (LSPs) (Note 3).

Since 2002, manufacturers involved in producing medicines in Hong Kong must comply with the **Good Manufacturing Practice (GMP — Note 4)**. As at March 2009, there were

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**Note 3:** *ASPs (commonly known as dispensaries or pharmacies) can sell both Part I and Part II poisons. LSPs (commonly known as medicine companies) can only sell Part II poisons.*

**Note 4:** *GMP is a quality assurance approach used by the medicine manufacturing industry worldwide to ensure that products are consistently produced and controlled according to quality standards appropriate to the products' intended use. The spirit of the GMP emphasises that the assessment of "good quality" should be based on scrutiny of the manufacturing process and not by testing of the products produced. Hong Kong has adopted the GMP guidelines promulgated by the World Health Organisation.*



about 40 manufacturers (i.e. 25 GMP manufacturers and 15 non-GMP manufacturers — Note 5), 860 wholesalers, 240 I/Es, 500 ASPs and 3,300 LSPs.

1.8 The DH carries out the following enforcement activities to monitor the operations of dealers:

- (a) inspection of dealers' activities;
- (b) market surveillance of medicines;
- (c) test purchases;
- (d) investigation of complaints and instigating prosecutions; and
- (e) joint operations with the Hong Kong Police Force (Police) and the Customs and Excise Department (C&ED) against illegal sale of medicines, and counterfeit medicines.

### **Control of medicines**

1.9 **Under the PPO, medicines must be registered with the Board before sale in Hong Kong (Note 6).** In line with international practice, the DH only allows medicines which are safe, efficacious and of good quality to be registered. Medicine safety and efficacy are mainly demonstrated through clinical trials. As regards assurance of medicine quality, the DH relies on the licensing requirement for local manufacturers to comply with the GMP or, in the case of imported medicines, the certification of GMP by corresponding overseas authorities. Dealers in Part I poisons are required to keep a record of transactions with supporting documents which are open to DH inspection. The same record keeping arrangement applies to antibiotics governed by the ABO.

1.10 The DH also carries out post-market controls to monitor the safety, efficacy and quality of medicines on the market. Such controls include market surveillance, test

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**Note 5:** *GMP manufacturers have to comply with GMP requirements. Of the 25 GMP manufacturers, 24 were certified to manufacture medicines whereas one was certified to package medicines only. Non-GMP manufacturers (excluding 3 who are only allowed to manufacture/package animal feed supplements) are not allowed to manufacture medicines themselves, but have to outsource their manufacturing to GMP manufacturers.*

**Note 6:** *Under the PPO, the sale of an unregistered medicine is an offence carrying a maximum penalty of \$100,000 and 2 years' imprisonment.*

purchases, investigation of complaints, joint operations (see para. 1.8(b) to (e)) and monitoring of adverse drug reaction reports (Note 7).

1.11 **The import and export of medicines are subject to licensing control.** In accordance with the **Import and Export Ordinance (I&E Ordinance — Cap. 60)**, dealers are required to apply for an **import licence (IL)** and an **export licence (EL)** for medicines to be imported/exported. In addition to ILs/ELs issued under the I&E Ordinance, an IL/EL under the DDO is also required for import and export of DDs. Furthermore, a removal licence is required for DDs in transit.

### **Incidents in early 2009**

1.12 A series of incidents occurred in early 2009 involving unsafe and unregistered medicines (see examples at Appendix C). They have caused great public concern and have somewhat shaken Hong Kong people's confidence in local medicines. They cast doubts on the adequacy and performance of the existing regime for the regulation and control of medicines. The DH has immediately taken the following actions:

- (a) investigating all incidents;
- (b) issuing written advice and reminders to manufacturers, wholesalers, I/Es, retailers and professional associations; and
- (c) conducting an additional round of inspections of the 25 GMP manufacturers (see para. 1.7) to assess their work in assuring the safety, efficacy and quality of their products, particularly the identification and control of microbiological hazards.

### ***Setting up of Review Committee***

1.13 In March 2009, the Food and Health Bureau (FHB) announced the setting up of a **Review Committee** to undertake a comprehensive review of the existing regulatory regime for the regulation and control of medicines. The Review Committee is chaired by the Permanent Secretary for Food and Health (Health) and comprises members from the

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**Note 7:** *Under an adverse drug reaction reporting programme, healthcare professionals are encouraged to report to the DH signs and symptoms which are uncommon under normal medicine dose. Besides, under a collaborative programme between the DH and the Hospital Authority, when the latter encounters patients suspected to have been affected by the consumption of harmful products, it refers the products to the DH for follow-up investigation.*

pharmaceutical sector, medical profession and other fields. The Review Committee held its first meeting in April 2009 and was expected to complete its review by the end of 2009.

1.14 To support the work of the Review Committee, the Director of Health has set up a **Task Force** to review the existing control of the medicine supply chain as well as the control of medicines, and to make recommendations to the Review Committee. The DH has also enlisted the assistance of two overseas consultants to support the work of the Task Force.

### **Audit objectives and scope**

1.15 As mentioned in paragraph 1.3, this audit review mainly covers the control of western medicines. The Audit Commission (Audit) started this audit in late January 2009, two months before the onset of the 2009 medicine incidents, with the objective of examining the adequacy of the DH's work in the control of the trade and medicines. The audit review has taken into account the subsequent developments, i.e. the 2009 medicine incidents and the setting up of the Review Committee and the Task Force.

1.16 Audit has found that there were inadequacies in the following areas:

- (a) importation of unregistered medicines (PART 2);
- (b) inspection of dealers' activities and other enforcement actions (PART 3);
- (c) medicine testing, recalls and public alerts (PART 4);
- (d) licence-refusal criteria, prosecutions and disciplinary actions (PART 5); and
- (e) public information and internal support (PART 6).

### **Overall audit recommendation**

1.17 In this report, Audit has identified room for improvement in various areas in the existing regulatory regime. **Audit has recommended that the Secretary for Food and Health should take into account the audit observations and recommendations in this report in formulating the Government's strategy for building up an effective regime for the regulatory control of medicines in Hong Kong.** As at September 2009, there

were 39 pharmacist inspectors (PIs — Note 8) in the establishment of the Inspection and Licensing Section and the Clinic Service and Pharmaceuticals Import/Export Control Section of Pharmaceutical Service of the DH (see organisation chart at Appendix D). Audit notes that, as part of its review, the Review Committee will assess the resource implications in support of the enhanced regulatory framework.

### General response from the Administration

1.18 The **Secretary for Food and Health** welcomes the audit review. He has said that:

- (a) the Review Committee is conducting a comprehensive review of the existing regulatory regime and is working closely with various stakeholders to identify different enhancement measures for the effective control of medicines. The review will be completed by the end of 2009 (see para. 1.20);
- (b) the FHB will take into account the audit observations and recommendations in implementing the recommendations of the Review Committee; and
- (c) the FHB will also work with the DH regarding the additional resources required to support the enhanced regulatory framework.

1.19 The **Director of Health** has said that he appreciates the effort of the Audit team in auditing the DH's work on the control of western medicines and is grateful for the team's hard work.

### More recent development

1.20 On 23 October 2009, the Review Committee announced a range of recommendations which would enhance medicine safety, better protect patients and consumers, and promote public health (see Appendix E). The Permanent Secretary for Food and Health (Health), as the Chairman of the Review Committee, said that:

- (a) the review of the Review Committee covered all aspects of the medicine regulatory regime and the medicine supply chain, from manufacturing, distribution, procurement, medicine supply and delivery to the public and private

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**Note 8:** *One Chief Pharmacist heading the Pharmaceutical Service and five Senior Pharmacists in the two Sections were not counted.*

sectors, to control of medicines, pharmacovigilance (Note 9) as well as risk communication, education and training;

- (b) a risk-based approach was adopted to assess the risks in terms of the nature of the medicines, and the potential level of harm of these medicines; and
- (c) an enhanced inspection and audit system for the supply chain was also proposed.

The Review Committee would start to prepare its final report on the detailed recommendations which will be completed at the end of 2009.

### **Acknowledgement**

1.21 Audit would like to acknowledge with gratitude the full cooperation of the staff of the DH, the FHB, the C&ED and the Trade and Industry Department (TID) during the course of the audit review. In particular, Audit would like to thank the C&ED for its investigation work in PART 2.

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**Note 9:** *Pharmacovigilance refers to activities relating to the detection, assessment, understanding and prevention of adverse effects of medicines.*

## **PART 2: IMPORTATION OF UNREGISTERED MEDICINES**

2.1 This PART examines the problems of importation of unregistered medicines for re-export purposes, and the importation of medicines without licences. As the procedures governing the importation of western and Chinese medicines are largely the same, this PART addresses the problems common to both.

### **Licensing control and enforcement**

2.2 Medicines must be registered with the Board before sale (see para. 1.9). In Hong Kong, 70% of medicines were imported (see para. 1.4). As unregistered medicines may not have passed any tests on safety, efficacy and quality as required under the PPO, they can threaten lives. In recent years, the sale of unregistered medicines in the local market has become a growing public concern (Note 10). Such unregistered medicines can either be locally manufactured, or illegally/improperly imported into Hong Kong.

2.3 As mentioned in paragraph 1.11, the import and export of medicines are subject to licensing control. Section 3 of the I&E Ordinance empowers the Director-General of Trade and Industry to issue any licence required under the Ordinance. Under sections 6C(1) and 6D(1) of the I&E Ordinance, no person shall import or export medicines except under and in accordance with a licence issued by the TID (Note 11). Since September 2002, the TID has delegated the powers and duties for the issue of licences on medicines to specified public officers in the DH. With the commencement of licensing control on the import and export of Chinese medicines on 11 January 2008, the TID has further delegated the powers and duties for the issue of licences on proprietary Chinese medicines (pCms) and 36 specific Chinese herbal medicines to specified public officers in the DH since the same day.

2.4 Illegal/improper imports of unregistered medicines may include importation of medicines without licences or situations when unregistered medicines are imported for re-export purposes, but ultimately have ended up being sold in Hong Kong.

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**Note 10:** *For example, in July 2009, the DH urged the public not to consume certain virility products that contained undeclared western medicine ingredients. Some elderly males had developed profound and prolonged hypoglycaemia after taking such unregistered products. The DH reported that since February 2008, there had been 79 patients affected by such category of products and three had died.*

**Note 11:** *Under the I&E Ordinance, the import/export of medicines without a licence is an offence carrying a maximum penalty of \$500,000 and 2 years' imprisonment.*

### *Roles and responsibilities of three relevant departments*

2.5 Three government departments are involved in the licensing control and enforcement of ILs and ELs on medicines. They are the DH, the C&ED and the TID. Their roles and responsibilities are as follows:

- (a) **DH.** The DH is empowered by the TID to issue licences (see para. 2.3). According to the I&E Ordinance, the DH may attach such conditions as it sees fit, and may cancel, revoke or suspend any licences issued. Being the licensing authority, it plays a primary role in preventing the improper import of medicines into Hong Kong by imposing suitable import and export licensing control;
- (b) **C&ED.** The C&ED provides support to the DH through enforcement of the provisions of the I&E Ordinance on the import and export of medicines, including the conduct of **customs control** through inspection of documents (such as manifests and ILs/ELs) and, where necessary, physical examination of the medicines. Because of the voluminous amount of cargoes entering and leaving Hong Kong every day, customs control is enforced through selective checks and examination based on risk assessments and intelligence received; and
- (c) **TID.** The TID provides manifest checking support to the DH and carries out its checking in accordance with DH's requirements. Its Manifest Checking Unit selectively checks **manifests** (Note 12) submitted by cargo carriers (shipping companies, airlines and transportation companies) to see that prohibited goods (such as medicines) reported are covered by licences (ILs and ELs — Note 13), and that the licence particulars match with the manifest particulars. Any irregularities will be reported to the DH.

### *Audit examination*

2.6 Audit examined the following issues in this PART:

- (a) importation of unregistered medicines for re-export purposes (paras. 2.7 to 2.24); and
- (b) importation of medicines without licences (paras. 2.25 to 2.35).

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**Note 12:** *Cargo carriers are required under the I&E Ordinance to send to the TID, within 7 days after receiving the ILs from the licensed traders (or 14 days after medicine exportation in case of ELs), manifests giving full shipment details for the medicines imported (or exported), together with the licensed traders' original licence copies (see para. 2.25).*

**Note 13:** *Under a Transshipment Cargo Exemption Scheme operated by the TID, cargo carriers or freight forwarders registered with the TID are exempted from obtaining ILs and ELs for transshipment of medicines.*

## Importation of unregistered medicines for re-export purposes

### *Issue of ILs and ELs*

2.7 In 2008, the DH issued some 45,000 ILs and 88,000 ELs for medicines (Note 14). To apply for ILs and ELs, the medicines must have been registered with the Board (Note 15), and the applicant must be a licensed trader (i.e. a manufacturer, wholesaler or an I/E) and must be the holder of a Hong Kong registration certificate of the medicine (Note 16). **However, medicines imported for re-export purposes are not required to be registered.** The DH will issue an IL for the importation of medicines for re-export purposes when the applicant has met the following conditions:

- (a) he is a licensed trader;
- (b) he has declared on the IL application form that the medicines to be imported are for re-export purposes;
- (c) he has declared on the application form the country to which the medicines will subsequently be re-exported; and
- (d) he can provide supporting documents to show details of the medicines.

As the Pharmacy and Poisons Regulations of the PPO (PPRs — Cap. 138A) allow unregistered medicines to be imported for re-export purposes (Note 17), the DH does not take steps to verify if medicines being applied for such importation have been registered in Hong Kong.

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**Note 14:** *They included some 3,000 ILs and 4,900 ELs issued for pCms, and 36 ILs and 18 ELs for Chinese herbal medicines. In the DH, ILs and ELs for western medicines and pCms are issued by the Clinic Service and Pharmaceuticals Import/Export Control Section of Pharmaceutical Service whereas those for Chinese herbal medicines are issued by the Chinese Medicine Division.*

**Note 15:** *The applicant is required to provide full details of the medicines to be imported or exported (such as description, quantity, literature and medicine insert) and has to state the Hong Kong Registration Number for the medicines on the IL/EL.*

**Note 16:** *If the applicant is not the holder of a Hong Kong registration certificate of the medicine to be imported, the application must be supported by a written authorisation from the relevant medicine registration certificate holder.*

**Note 17:** *Medicines which do not require to be registered with the Board also include drug substances imported by manufacturers for manufacturing their own medicines, and medicines imported by or under the direction of a doctor or a dentist for the treatment of a particular patient.*



2.8 Under the present arrangement, an IL/EL will usually be ready for collection one working day after the submission of an application with the DH. When the licensed trader collects medicines (for imports) or despatches medicines (for exports), he will hand over the original IL/EL to the cargo carrier who will forward it to the TID together with the manifest (Note 18). The DH keeps copies of the ILs and ELs issued on file. An IL is valid for 6 months from the date of issue whereas an EL is valid for 28 days.

## Audit observations and recommendations

### *Importation of medicines for re-export*

2.9 As mentioned in paragraph 2.7, the DH will issue an IL for the importation of medicines (whether they are registered or not) if the medicines are purported to be for re-export purposes. **This will provide an opportunity for abuse if proper controls are not put in place to ensure that such imported medicines have duly been re-exported subsequently.** The importation of unregistered medicines (with no guarantee of their quality) would pose a public health risk if they, instead of being re-exported, have been distributed for sale or consumption in the local market.

2.10 Audit has however found that the DH does **not** have adequate controls to track the movements of imported medicines for re-export purposes, as shown below:

- (a) ***Weekly referral of only 18 licences to C&ED for consignment checking.*** The DH issues about 2,560 licences (ILs and ELs) a week. However, only 18 (0.7% of 2,560) licences are referred to the C&ED a week for post-shipment consignment checking. The purpose of the C&ED consignment checking is to ensure that the medicines being applied for importation or exportation have in fact been imported or exported in accordance with the licences issued (Note 19). The C&ED has been providing such enforcement support to the DH since September 2002. The referral of 18 licences a week has remained unchanged

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**Note 18:** *The TID used to detach the original licence from the manifest and return it to the DH for matching against/filing together with the respective departmental copy of licences. Since April 2004, the procedures have been streamlined in that the TID no longer returns it to the DH.*

**Note 19:** *The C&ED will forward the results of the checking to the DH for follow-up action. Based on the results, the DH will, if necessary, issue warning letters on irregularities noted, e.g. if the licensed traders have imported more quantities than those approved in the IL or medicines have been exported based on an expired EL, provided that there is no fraudulent intent.*

since that time (Note 20). The licences for referral are randomly selected by the DH using its computer system. Because the selection is not made with reference to any risk factors, licences with higher risks (such as ILs for importing unregistered medicines for re-export purposes) have not been given a higher priority to be selected for examination;

- (b) **No time limit for re-export.** Although ILs are valid for 6 months, there is no time limit within which the imported medicines must be re-exported;
- (c) **No returns on medicine movements.** The DH does not require the licensed traders to furnish any returns on the movement of medicines imported for re-export purposes (Note 21). Although licensed traders are required under the DDO, the ABO and the PPRs to keep records of transactions relating to DDs, antibiotics and Part I poisons, and the DH examines such records (e.g. the DDs register and the poisons records) in its inspections of the traders' premises, these measures cannot provide adequate assurance that medicines imported for re-export purposes have all been properly accounted for. This is because:
  - (i) licensed traders are not required under the PPRs to keep records of import/export transactions for Part II poisons and non-poisons. In fact, under the existing procedures (except in the case of pCms), the DH has not required licensed traders to provide, in their licence applications for the importation of unregistered medicines for re-export purposes, a complete formula of the ingredients of the medicines issued by the manufacturer. The DH also will not inform the traders the classification of the unregistered medicines imported (e.g. Part I or Part II poisons). As a result, there is a risk that some unregistered medicines containing Part I poisons (but not stated in the supporting documents to the licence applications) may not have been properly classified for recording purposes;

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**Note 20:** *Before the licensing control on the import and export of Chinese medicines was introduced (see para. 2.3), the DH had requested the C&ED to conduct more consignment checking, but the C&ED could not entertain it because the DH request was not timely raised to enable the C&ED to seek additional resources. At a meeting with the DH in August 2007, the C&ED reiterated that due to limited resources, it could only verify 18 licences a week.*

**Note 21:** *In the absence of any returns, the DH does not know if the licensed traders have made any false declarations or have furnished incorrect information in his licence application. Section 36 of the I&E Ordinance stipulates that any person who makes any statement or furnishes any information which is false or misleading in a material particular or omits any material particular shall be guilty of an offence, and shall be liable on conviction to a fine of \$500,000 and to imprisonment for 2 years.*

- (ii) the C&ED staff responsible for consignment checking are not authorised to enforce the PPO and its subsidiary regulations. Therefore, the C&ED consignment checking does not cover the proper recording of the import/export transactions in the licensed traders' records; and
- (iii) in the DH inspection of wholesalers and I/Es' premises (with some not inspected for over one year — see para. 3.20), the DH only conducted test-checks from the licensed traders' poisons records to their licence copies. There was no checking of transactions from the DH departmental licence copies (see para. 2.8) to the poisons records to ensure completeness of recording. Case 8 in paragraph 5.12 is an example to demonstrate the omission in recording and the inadequacy of DH checking;
- (d) *Additional administrative measures adopted for certain medicines inadequate.* Since May 1999, the DH has adopted an additional administrative arrangement to control the importation of certain medicines for re-export purposes. Such medicines include slimming products that contain “Orlistat” and virility products that contain “Sildenafil” (both are Part I poisons). For these medicines, the DH has required the licensed traders to apply for ELs at the same time as they apply for ILs. However, such arrangement does not provide adequate assurance that the medicines imported will in fact be re-exported. This is because the DH does not require the licensed traders to inform it whether the ELs have been used and, if not used, to apply for their cancellation and to keep the DH informed of the disposal of the imported medicines; and
- (e) *Supporting roles played by TID and C&ED.* Although the TID is responsible for manifest checking (see para. 2.5(c)), it only conducts selective checks on manifests submitted by cargo carriers to see that prohibited goods (such as medicines) are covered by licences. As the TID only receives licence copies from the cargo carriers (see para. 2.8), it does not have complete information of the licences issued by the DH. The same applies to the C&ED which could only follow up on the 18 licences referred to it weekly for consignment checking (see (a) above).

2.11 Given the inadequate controls, there is a possibility that some unregistered medicines purportedly imported for re-export purposes might have been distributed for sale or consumption in Hong Kong. **There is a need for the Government to ascertain the magnitude of the problem, conduct an impact assessment (e.g. assess the degree of health risk to consumers) and develop a strategy to tackle it.**

*Impact of inadequacies in control*

2.12 To assess the impact of the inadequacies in control, Audit performed the following tests:

- (a) Audit scrutinised the ILs issued by the DH in one selected month (November 2008) and found that, out of 3,251 ILs issued, 424 (13%) ILs related to the **importation of medicines for re-export purposes**. (None of these 424 ILs related to the importation of DDs.) Audit also found that only 2 of these 424 ILs had been included in the 18 licences weekly referred to the C&ED for consignment checking;
- (b) Audit examination of the 424 ILs indicated that for the majority of them, the licensed traders had **not** provided a complete formula issued by the manufacturer of the ingredients of the medicines. Even with the assistance of DH staff, Audit could not ascertain if the 424 ILs related to the importation of registered medicines. This was because the medicine particulars on the ILs were inadequate to confirm if the medicines had been registered with the Board (Note 22). Audit also requested the DH to ascertain if the medicines of the 424 ILs had in fact been imported and if so, had subsequently been re-exported. However, enquiry indicated that the DH did not maintain such a record;
- (c) a scrutiny of the 424 ILs showed that some of the imported medicines were large in quantity and/or significant in value. A few examples are shown below:

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**Note 22:** *Under the PPO, various medicine particulars have to be registered. These include the name, the specifications, the label, the package insert, the names and addresses of the manufacturer and the registration certificate holder, the dose form, the quantity of the dose contained in its unit package, the name and quantity of all its active ingredients, and its proposed indication, dosage and route of administration. If any one of these particulars has changed without approval, the medicine will not be regarded under the PPO as registered.*

Medicine (Note)	Quantity applied for importation	Declared value (\$ million)	Country for re-export
(i) Virility product	240 kg	93.6	Australia
(ii) Raw materials (with Florfenicol as one major ingredient)	7,368 kg	20.6	Southeast Asia, Germany, Ireland and USA
(iii) Virility product	1,200 bottles	2.6	Japan
(iv) Gastrointestinal pill	45,000 dozens	1.4	Mainland
(v) Undefined (with Avilamycin A as one major ingredient)	300 bags	1.2	Mainland

*Note: In early October 2009, the DH informed Audit that the medicines in (i) to (iii) and (v) above belonged to Part I poisons/antibiotics, while the medicine in (iv) was a non-poison.*

Audit checking against DH records indicated that these five medicines were not registered in Hong Kong;

- (d) in early July 2009, Audit requested the C&ED to verify if the medicines in 15 ILs (involving 13 licensed dealers — Note 23) had in fact been re-exported. The results, as at 28 September 2009, were as follows:

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**Note 23:** *Of these 15 ILs, 12 ILs were selected from the 424 ILs (see para. 2.12(a)) and 3 were issued in May, June and October 2008 to a dealer whose Wholesale Poisons Licence was revoked in October 2008 (see para. 5.10). The validity periods of the ILs should have expired by the time of audit referral.*

- **Medicines re-exported.** 3 ILs were found in order. The medicines imported had been re-exported within 3 months under valid ELs.
- **No shipments.** For 2 ILs, there were no import shipments. The 2 ILs had not been cancelled because the DH did not have such a requirement.
- **Irregularities found.** The remaining 10 ILs had one or more of the following irregularities:

- **3 ILs involved improper sales of imported medicines locally instead of re-export (Note). No approval from the DH had been obtained.**

1 IL involved the importation of 8,000 vials of a medicine (containing Part I poisons). 911 vials (11%) were delivered to another licensed dealer for local sale (on consignment terms) 3 weeks after importation.

2 other ILs involved the importation of 3 medicines in May and November 2008 by one dealer. It was found that 8,853 bags (94% of 9,404 bags imported), 400 bottles (80% of 500 bottles imported) and 637 bottles (32% of 1,978 bottles imported) of three respective medicines had already been sold in the local market.

- **All or part of the medicines imported under 6 ILs were still held in stock or stored in unapproved places.**

For 1 IL, the medicines (declared to contain Part I poisons) had been imported in June 2008, but, as at the end of August 2009, were still in stock (for 14 months) and had not yet been re-exported. In September 2009, some medicines were seized by the DH as the dealer, whose licence had been revoked, was suspected of illegally possessing Part I poisons (see Fact 2 in Case 8 in para. 5.12).

For 5 ILs, 19%, 20% and 6% (for 2 medicines imported under 1 IL), 34%, 36% and 68% of the respective imported medicines were still in stock (for 7 to 16 months) and, as at the time of C&ED inspection (July to September 2009), had not yet been re-exported. For 2 of these 5 ILs, there were indications that the places where the medicines were stored were not premises/warehouses approved by the Board/DH.

- **8 ILs involved short shipments in the importation of medicines, with the short shipment quantities ranging from 9% to 81%.**
- **1 IL involved re-export of medicines to three countries other than that declared on the licence.**

*Note: In September 2009, the C&ED informed Audit that it would consider prosecuting the dealers for false declarations on ILs. In early October 2009, the DH also informed Audit that some of the medicines sold locally were registered ones, and there should be no public health impact.*

As the medicines imported may be unregistered, Audit is concerned that some of them had been sold locally instead of being re-exported. Besides, because medicines usually have a short shelf life of 2 to 3 years, Audit is also concerned that some of the medicines purportedly for re-export were still in stock 7 to 16 months after importation and some were kept in places which had not been approved by the Board/DH for storage. The situation is not entirely satisfactory; and

- (e) in early July 2009, Audit staff attended as an observer in a DH routine inspection of a wholesaler's premises. Based on the DH records, this wholesaler held a Wholesale Poisons Licence (WPL) and an antibiotics permit. Audit noted that, although the wholesaler did not hold any Hong Kong medicine registration certificate, he was very active in the importation and exportation of medicines (Note 24). Details are in Case 1.

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**Note 24:** *In early October 2009, the DH informed Audit that, while it was correct to say that for medicines imported for local consumption, wholesalers and I/Es must either hold a relevant Hong Kong certificate of registration or have been authorised by the certificate holder, unregistered medicines might be imported for re-export purposes (see para. 2.7). No Hong Kong registration certificate was required for importing medicines for re-export purposes.*

## Case 1

### Audit attendance at a DH inspection of a wholesaler's premises

#### *Case particulars*

1. Based on the DH records, for the 14 months ended 31 August 2009, the wholesaler had been issued with 12,200 licences (600 ILs and 11,600 ELs). Many of these licences related to the importation of large quantities of slimming and virility products, and their re-exports by multiple shipments in small quantities.
2. During the inspection (July 2009), at Audit's request, the DH examined the wholesaler's records on a few ILs. Audit noted that:
  - (a) the wholesaler was involved in import and export of 250 medicines, all of which were **unregistered medicines** (belonging to Part I poisons and antibiotics);
  - (b) although the wholesaler had kept computer records on the import and export of the unregistered medicines, all exports were sent out to another country by registered post. Only certificates of posting for the registered packets were kept. The contents of the postal packets were not known; and
  - (c) there was no checking of the export transactions by the DH from the poisons records to independent documentary evidence (such as purchase orders issued by overseas buyers, which were then not readily produced by the wholesaler) to support the sales.

#### *Audit comments*

3. Audit considers that the controls over the re-export of imported medicines are inadequate. Under the I&E Ordinance, cargo carriers will only accept medicines with licences for import or export. But, in this case, because all exports were sent out by postal packets, no cargo carrier service was involved (Note). As such, there is inadequate assurance that all the unregistered medicines (Part I poisons and antibiotics) imported by the wholesaler for re-export purposes have in fact been re-exported. There is a risk that some of the unregistered medicines might have been distributed for sale or consumption in the local market.

*Source: DH records and Audit observations*

*Note: In situations when no cargo carrier service is involved (e.g. when medicines are exported by post), there is no assurance that the wholesaler has re-exported the medicines in accordance with the ELs. Based on the Post Office Guide, the wholesaler (as the sender) is responsible for complying with the export licensing requirements.*



2.13 **Audit considers that, unless proper control is in force to track the movements of unregistered medicines, there are opportunities for abuse.** It can be seen from the audit tests in paragraph 2.12 that the DH issued quite a large number of ILs a month for the importation of medicines for re-export purposes. Some of these imported medicines were large in quantity or significant in value. Unregistered medicines imported this way would pose a public health risk if they have been distributed for sale or consumption locally. **Audit has further found that the DH had not stepped up control in this regard although it was aware of such risk as early as 1999 (see para. 2.14).**

*Discussions by the Board and LegCo Health Panel*

2.14 The following chronology of events shows the discussions on the subject by the Board with the Legislative Council (LegCo) Panel on Health Services (Health Panel) and the pharmaceutical trade from February 1999 to December 2000:

Month/year	Event
(a) February 1999	<p>The LegCo Health Panel had a meeting with the Board and a pharmaceutical trade association (Note 25) to discuss the control of unregistered medicines in Hong Kong. At the meeting, the then President of the association explained the various channels through which unregistered medicines could be illegally imported and the need for various government departments (the DH, the TID and the C&amp;ED) to work closely with the pharmaceutical trade with a view to closing the loophole. At the meeting, the Health Panel was also informed that the Board would formulate measures to tighten the control on the import of unregistered medicines for re-export.</p>
(b) January 2000	<p>At another meeting, the Health Panel was informed by the Board that, having considered the feedback and suggestions from the pharmaceutical trade, the TID and the C&amp;ED, the Board decided in June 1999 that a wholesaler or an I/E wishing to bring unregistered medicines into Hong Kong for re-export purposes should satisfy <b>one</b> of the following two conditions:</p> <ul style="list-style-type: none"> <li data-bbox="549 981 1348 1081">(i) production of a letter of authorisation from the manufacturer allowing the wholesaler or I/E to bring the medicine into Hong Kong for re-export purposes; or</li> <li data-bbox="549 1122 1348 1290">(ii) application for IL had to be accompanied by application for EL, together with production of documentary evidence (such as a purchase order or a Letter of Credit) to show that the unregistered medicines to be imported would in due course be re-exported.</li> </ul>
(c) March 2000	<p>The Board informed the trade that, after considering the feedback from interested parties, it had decided to revise the proposal in (b) above. Instead, it would <b>only</b> approve an application for IL if it was accompanied by an application for EL and there was documentary evidence (such as purchase order or Letter of Credit) to show that the unregistered medicine would be re-exported (see (b)(ii) above). In the same month, the Board also informed the Health Panel of its decision and that the proposed revised arrangement would take effect from <b>2 January 2001</b>.</p>

**Note 25:** *In July 1998, the pharmaceutical trade association wrote a letter to the Board stating the association's position on the importation of unregistered medicines and the proposed ways to tighten up the medicine re-export system. In November 1998, the then Chairman of LegCo Health Panel approached the Board for more information. Representatives of the association were also invited to attend the Health Panel meeting of 8 February 1999.*

Month/year	Event
(d) May and July 2000	The Board received representations from some traders on the practical difficulties they would encounter in complying with the proposed revised arrangement. In July 2000, the Board also received a request from the pharmaceutical trade association (see (a) above) to drop the proposed revised arrangement which “is showing a detrimental effect to many of its member companies”. The association considered that there was already a system to regulate medicine transactions.
(e) September 2000	The Board consulted the trade on <b>an alternative control measure</b> of requiring traders to maintain a full record on the movement of unregistered medicines, and documentary evidence to prove that the imported unregistered medicines were actually re-exported. Such records and supporting documents should be kept for 2 years and would be subject to inspection by DH.
(f) November 2000	The Board noted that as at 15 November 2000, 178 of 184 replies to a survey of traders (in (e) above) indicated support to the alternative control measure.
(g) December 2000	<p>The Board informed the trade that:</p> <ul style="list-style-type: none"> <li>(i) it had decided to adopt the alternative control measure. However, because legislative amendments would be required (and this would take time), the trade could continue importing unregistered medicines for sale elsewhere “in accordance with the prevailing rules and principles” (i.e. to continue their current practice of applying for ILs for importing medicines for re-export purposes); and</li> <li>(ii) it would inform the trade of the implementation plan for the alternative control measure once legislative amendments had been approved by LegCo.</li> </ul>

2.15 Since December 2000, there had been no progress in the submission of legislative proposals to LegCo.

*Delay in addressing the loophole*

2.16 Audit is concerned that for some 9 years (2001 to 2009), the DH had continued to allow the importation of unregistered medicines for re-export purposes, without installing proper controls. There was no requirement for traders to maintain a proper record on the movement of such imported medicines, and to make available such records for DH

inspection. There was again no requirement for traders to furnish any returns on the re-export of the medicines to the DH (see para. 2.10(c)).

2.17 **The fact that there has been a loophole in regulating the importation of unregistered medicines for re-export purposes is undesirable. Audit considers that the DH needs to take measures to plug the loophole without delay.** Such measures may include the following:

- (a) introducing appropriate legislative amendments as early as possible;
- (b) setting up a proper system (in consultation with the TID and the C&ED) to track the movements of the medicines imported for re-export purposes; and
- (c) strengthening the DH system for referring licences to the C&ED for post-shipment consignment checking.

#### *Use of computer system to track movements of unregistered medicines*

2.18 At a meeting in 1999 held between a number of Board members and the pharmaceutical trade association, the latter suggested that the Government should consider devising a computer system, similar to the TradeNet System in use in Singapore (linked up with a new system since 2007 — TradeXchange System), to monitor the import and export of medicines. **Audit considers that the DH needs to proactively explore, in consultation with the pharmaceutical trade, the feasibility of developing a computer system to monitor the import and re-export of medicines. However, in strengthening import control, the DH needs to take care not to create cumbersome procedures which may cause inconvenience to the trade and discourage business.**

#### *Need to keep LegCo informed*

2.19 In March 2000, the Board informed the Health Panel that it would implement, with effect from January 2001, the revised arrangement of regulating the import of unregistered medicines for re-export purposes (see para. 2.14(c)). However, the Board had **not** informed the Health Panel of the subsequent developments, including the alternative control measure, the need for legislative amendments and the fact that little progress had subsequently been made.

#### *Audit recommendations*

2.20 **Audit has recommended that the Secretary for Food and Health (as the policy head overseeing medicine safety) should take the lead and, in collaboration with**

the Board, the Director of Health, the Director-General of Trade and Industry, and the Commissioner of Customs and Excise:

- (a) work out a proper strategy to plug the control loophole in the importation of unregistered medicines for re-export purposes, and implement the strategy without delay;
- (b) explore, in consultation with the pharmaceutical trade, the feasibility of developing a computer system to track the import and re-export of medicines, including the more effective flow of shipment and medicine information among the DH, the C&ED and the TID;
- (c) in devising measures to strengthen import control, take care not to create cumbersome procedures which may cause inconvenience to the trade and discourage business; and
- (d) keep the Health Panel informed of subsequent developments.

### **Response from the Administration**

2.21 The **Secretary for Food and Health** has said that:

- (a) he will explore the feasibility of controlling the importation of unregistered medicines for re-export purposes with the DH and other relevant bureaux and departments; and
- (b) the FHB will inform the Health Panel of the outcome of the discussion.

2.22 The **Director of Health** has said that:

- (a) under the I&E Ordinance, all medicines have to be covered by ILs/ELs. As explained in paragraph 1.9, medicines must be registered with the Board under the PPO. However, unregistered medicines may be imported for re-export purposes. Irrespective of whether the medicines are registered or unregistered in Hong Kong, licensed traders have to provide in their applications for IL/EL full details of the products to be imported/exported;
- (b) the DH notes Audit's concerns in paragraph 2.13 that the DH should step up the control measures on the importation of unregistered medicines. The DH agrees with Audit's view in paragraph 2.10(c)(iii) that, as part of the DH inspection of wholesalers' premises, there should be checking of transactions from the DH departmental licence copies to the poisons records to ensure completeness of recording. The DH has reminded PIs of this requirement;

- (c) the DH issues some 140,000 ILs/ELs a year, about 70% of which are Part I poisons and DDs. Of the other 30% of ILs/ELs, the majority are non-poisons, comprising mainly vitamins, medicated shampoo, pCms and raw materials from the Mainland for re-export to other countries. The remaining are Part II poisons which may be sold without the supervision of registered pharmacists;
- (d) to ensure that the relevant provisions of the I&E Ordinance are complied with, the C&ED conducts selective checks on import and export cargoes/postal packets at the air, land and sea boundaries. It is for the C&ED to decide the extent of checking required to give it a reasonable confidence level about compliance with the Ordinance. The C&ED also conducts post-shipment consignment checking on ILs/ELs selected by the DH;
- (e) to further ensure the integrity of the medicine control system, the DH conducts intensive market surveillance. The primary objective is to bring to justice persons dealing in unregistered medicines or products adulterated with western medicines for treating illnesses;
- (f) there is a mechanism under the PPO and the ABO for the DH to monitor the movements and transactions of Part I poisons and antibiotics (see para. 1.9), which account for four of the five examples quoted by Audit in paragraph 2.12(c). The second last example is a non-poison (with value of \$1.4 million), which is of low risk to public health. In other words, indications are that most imported medicines large in quantity and/or significant in value are already covered by the more stringent PPO and ABO control requirements which have been strengthened following Audit's advice (see (b) above). The DH accepts that there is room for improvement as regards control on low-risk non-poisons and Part II poisons for re-export purposes, including the keeping of records for their movements; and
- (g) regarding the small number of licences randomly selected by the DH for post-shipment consignment checking by the C&ED (see para. 2.10(a)), the TID historically selected 18 licences for such checking. This quota has survived after the authority of issuing licences was delegated by the TID to the DH in 2002. The DH shares Audit's concerns that more licences should be selected for checking based on risk assessment, and is exploring with the C&ED the possibility of increasing the quota.

2.23 The **Director-General of Trade and Industry** has said that the TID would be pleased to render support to the DH as far as possible to implement the audit recommendations.

## More recent development

2.24 On 23 October 2009, the Review Committee (see para. 1.20) announced that it would consider the issue of import and re-export of medicines which were not intended for sale in the local market. The Review Committee indicated that since these medicines were not required to be registered in Hong Kong, it was important to ensure that they would not penetrate the local market and it was crucial to establish a mechanism to enhance the traceability of these medicines after they were imported.

## Importation of medicines without licences

2.25 The I&E Ordinance has provided that no person shall import or export prohibited goods (e.g. medicines) except under and in accordance with an IL or EL, and import/export without a licence is an offence (see para. 2.3). The Ordinance has also stipulated that:

- (a) **For imports:** a person to whom an IL has been issued shall present the licence to the cargo carrier within 7 days after the goods were imported. On presentation of the IL, the cargo carrier may release the goods to the licensed trader and shall, within 7 days after receiving the licence, deliver it together with the manifest to the TID; and
- (b) **For exports:** a person to whom an EL has been issued shall present the licence to the cargo carrier before export. The carrier shall, within 14 days after the date on which the prohibited goods are exported, deliver the licence and the manifest to the TID.

## Audit observations and recommendation

2.26 Audit conducted tests to ascertain if medicines have duly been imported or exported under and in accordance with a licence. Because the impact of importation without licences is greater, Audit focused on reviewing import transactions.

2.27 At the request of Audit, in May and June 2009, the C&ED ran a computer program to extract the import and export transactions over a period of 15 months (January 2008 to March 2009) for selected wholesalers and I/Es. The information was extracted from records of electronic manifests (e-manifests — Note 26) submitted by cargo carriers and from import/export declarations (Note 27) submitted by wholesalers or I/Es.

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**Note 26:** *The system for electronic submission of manifests has commenced operation since 2003. It enables cargo carriers (except the road mode of transport) to submit manifests electronically to the Government via a private sector front-end service provider.*

**Note 27:** *Under the I&E (Registration) Regulations of the I&E Ordinance, every person who imports or exports goods (including medicine) is required to lodge with the C&ED an import or export declaration within 14 days after the importation or exportation of the goods.*

- 2.28 Audit examined the import and export transactions and noted the following:
- (a) it was difficult to determine, solely based on the goods descriptions stated in the e-manifests, that the imported/exported goods were medicines. A few examples are “STONEFISH ANTIVENOM”, “GENCLONE” and “FLOGOPROFEN”. DH advice was required to confirm whether these goods were medicines which had to be supported by licences;
  - (b) there were also cases when medicines were imported/exported by the wholesalers and I/Es, but no licence information (e.g. IL number) was recorded in the manifests (Note 28);
  - (c) some of the medicines imported without IL/EL information in (b) above were **unregistered medicines**. Examples are “SEATONE”, “VIASPAN” and “DERMATIX GEL”;
  - (d) Audit selected three wholesalers (Note 29) for examination. From an examination of these wholesalers’ import and export transactions on medicines for three months (from October to December 2008), Audit found that no licence information was recorded for 57% of such transactions (Note 30), indicating that some medicines might have been **imported/exported without licences**; and
  - (e) in early July 2009, Audit referred 28 suspected transactions of the three wholesalers in (d) above to the C&ED for investigation. As at 28 September 2009, the results of the investigation were as follows:

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**Note 28:** *According to the I&E Ordinance, a manifest shall contain the particulars of the cargo, which include, where appropriate, the IL/EL number. The Ordinance also states that any copy of a manifest produced by the TID or the C&ED is admissible as evidence of the contents of the manifest in any proceedings under the Ordinance.*

**Note 29:** *The three wholesalers selected for examination were high-risk ones. Two were selected from those involved in the medicine incidents in early 2009 (see para. 1.12). The third was selected due to revocation of his WPL in October 2008 (see para. 5.10 and Case 8 in para. 5.12).*

**Note 30:** *Only complete transactions with matching medicine descriptions captured in both e-manifests and import/export declarations were counted. In the import/export declarations, special classification codes were provided for medicines.*



***Dealer 1 (13 import transactions)***

- 9 transactions were found to have involved the **importation of 385,000 boxes of unregistered medicines without IL (Note)**;
- 4 transactions were covered by valid ILs;

***Dealer 2 (8 import transactions)***

- 7 import transactions were covered by valid ILs, with the remaining 1 import transaction not relating to medicines;

***Dealer 3 (7 import/export transactions)***

- 1 import transaction was covered by a valid IL;
- 2 transactions involving the importation and re-export of medicines were covered by valid ILs and ELs (see Fact 1 in Case 8 in para. 5.12 for other irregularities found); and
- 4 export transactions were not related to medicines.

*Note: The C&ED will consider prosecuting the dealer for an offence of unlicensed importation of medicines under the I&E Ordinance.*

2.29 **The importation of medicines (particularly unregistered medicines) without a licence is a matter for concern.** Audit considers that there is a need for the Government to examine the circumstances leading to the improper importation of medicines into Hong Kong and explore measures to step up control.

2.30 The vigilance of the front-line staff of the C&ED is important in detecting the importation of medicines without licences. Given the difficulties in identifying medicines among imported goods (see para. 2.28(a)), there may also be a need to strengthen the training and support provided to C&ED front-line staff.

***Audit recommendation***

2.31 **Audit has recommended that the Commissioner of Customs and Excise, the Director of Health and the Director-General of Trade and Industry need to work closely together to explore ways to step up controls over the import of medicines.** Such

ways may include strengthening the training and support for C&ED front-line staff and the more effective flow of shipment and medicine information among the DH, the C&ED and the TID.

### **Response from the Administration**

2.32 The **Commissioner of Customs and Excise** accepts the audit recommendation. He has said that:

- (a) the C&ED will arrange with the DH to provide more training to C&ED front-line staff to enhance their capability in detecting medicines among imported goods;
- (b) the DH has agreed to provide the C&ED with an updated list of registered medicines on a regular basis to assist the C&ED in enforcing import/export control on medicines at the boundary; and
- (c) a working group will also be set up among the concerned departments to explore further means to enhance the information flow to assist the overall control of medicines.

2.33 The **Director of Health** welcomes the audit recommendation. He has said that the DH has been providing professional support to the C&ED in the enforcement of the I&E Ordinance, and will continue to collaborate closely with the C&ED. As mentioned in paragraph 2.32(c), a working group will be set up among the concerned departments to explore further means to strengthen the training/support to C&ED front-line staff and to enhance the information flow to assist the overall control on medicines.

2.34 The **Director-General of Trade and Industry** has said that the TID would be pleased to render support to the DH as far as possible to implement the audit recommendation.

### **More recent development**

2.35 On 23 October 2009, the Review Committee (see para. 1.20) announced that it would recommend strengthening the control of the import and export of medicines by deploying a designated team to provide advice to the C&ED at ports of entry and to undertake surveillance work.

## **PART 3: INSPECTION OF DEALERS' ACTIVITIES AND OTHER ENFORCEMENT ACTIONS**

3.1 This PART examines the DH's inspection of dealers' activities and other enforcement actions.

### **Importance of the DH's inspections**

3.2 Improper handling of medicines (including poisons) by dealers may cause risk to the public. The DH's inspections therefore play a very important role in ensuring that dealers comply with the medicine-related laws and regulations. Since May 2009, soon after the series of medicine incidents occurred (see para. 1.12), the DH has increased the number of PIs in its Inspection and Licensing Section from 27 to 36 to strengthen its inspection and other regulatory functions.

### *Audit examination*

3.3 Audit examined the following issues in this PART:

- (a) inspection of manufacturers' licensed premises (paras. 3.4 to 3.15);
- (b) inspection of wholesalers' and I/Es' licensed premises (paras. 3.16 to 3.26);
- (c) inspection of authorised and listed sellers of poisons (paras. 3.27 to 3.36);
- (d) market surveillance (paras. 3.37 to 3.41); and
- (e) test purchases (paras. 3.42 to 3.47).

### **Inspection of manufacturers' licensed premises**

3.4 Medicine manufacturers must first obtain a licence from the Pharmacy and Poisons (Manufacturers Licensing) Committee of the Board (ML Committee) before commencing operations. They have to meet certain licensing requirements before their applications for new licences and licence renewals (on a yearly basis) are approved. Since 2002, compliance with the GMP has been a mandatory licensing requirement.

3.5 GMP inspection is conducted annually on each manufacturer's premises by a team of two PIs. The inspection, which lasts one or two days, aims at ensuring compliance

with the GMP requirements. During inspections, all different GMP aspects will be examined for compliance against a checklist, and samples of medicines will be selected for laboratory tests to ensure quality (see para. 4.11). If there is minor non-compliance with any licensing conditions, the manufacturer will be instructed to remedy the situation and verbally reprimanded. For serious non-compliance, the ML Committee will consider revoking the licence or suspending it for such period as it thinks fit.

## Audit observations and recommendations

### *No surprise inspections*

3.6 **Hong Kong practice.** Some six months before the expiry of a manufacturer's licence (ML), the DH sent a notification letter and an application form for renewal of the ML to the manufacturer. Staff of the DH Inspection and Licensing Section would agree with the manufacturer on the date of the GMP inspection which was usually conducted two months before the expiry of the ML.

3.7 Because such GMP inspection was conducted on a **pre-arranged** basis, it provided an opportunity for the manufacturer to get well prepared. From 2006 to 2008, no manufacturer had been denied renewal of MLs or had been prosecuted. Audit considers that introducing surprise inspections helps ensure that manufacturers comply with the GMP requirements.

3.8 **Overseas practices.** Although most of the overseas health authorities conducted their GMP inspections on a pre-arranged basis, they also conducted surprise inspections — see examples below:

- **Australia.** The first GMP inspection for a new licence was always a pre-arranged one. Subsequent inspections might be either pre-arranged or unannounced. The need for a surprise inspection would arise, for example, from a recommendation of an internal review panel, or where other circumstances necessitated such a requirement.
- **UK.** Although the majority of their GMP inspections were pre-arranged, about 10% a year were surprise inspections.
- **USA.** GMP inspections could either be pre-arranged or unannounced, depending on, among other things, the inspection history of the manufacturers. A GMP inspection would usually take one week.

3.9 On 3 April 2009, the DH informed the Review Committee that it planned to conduct surprise checks on the 25 GMP manufacturers. In April and May 2009, the DH conducted surprise inspections of all GMP manufacturers' premises to ensure microbiological safety. During the inspections, samples of suspected high-risk medicines were also collected for microbiological testing. **Audit considers that the DH needs to uphold its efforts in conducting surprise inspections of manufacturers' premises.**

*Inadequacies in DH inspections*

3.10 The DH inspected all 37 manufacturers' premises (Note 31) once a year, with follow-up inspections (if required) in cases where irregularities had been found. Such follow-up inspections were usually conducted one to two months after the annual inspections. Audit noted the following inadequacies in the DH inspections:

- (a) ***No site inspection outside Hong Kong was conducted.*** Audit examined the inspection reports of a sample of 16 manufacturers and found that 3 of them had outsourced wholly or partially their manufacturing to contractors outside Hong Kong (all in the Mainland). Apart from taking steps to ensure that the contractors had obtained the relevant GMP certificates from corresponding authorities, the DH had not conducted any inspections of these contractors' premises (Note 32). For better assurance of the quality of medicines produced by the contractors, the DH needs to consider conducting inspections of their premises;
- (b) ***More frequent inspections were not conducted.*** All 37 manufacturers were inspected once a year before their MLs were renewed. Audit noted that some manufacturers had poor performance in the past or had conviction records, but they were not more frequently inspected. The DH needs to conduct more frequent inspections of these manufacturers. Case 2 is an example; and

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**Note 31:** *Of all 40 manufacturers (see para. 1.7), 3 are allowed to manufacture/package animal feed supplements only, and their MLs are renewed without any DH inspection.*

**Note 32:** *In the USA, if a manufacturer has outsourced all or part of its manufacturing to an overseas contractor, the Food and Drug Administration will inspect such overseas manufacturing premises. In Australia, the manufacturer is required to provide acceptable evidence of GMP compliance for the contractors' premises, and, if this is not available, inspections of the overseas manufacturers/contractors' premises will be arranged. In the UK, overseas inspections, with focus on the products to be imported, will be arranged.*

## Case 2

### DH inspection of a manufacturer's premises

#### *Case particulars*

1. Arising from a referral, the DH inspected a manufacturer's premises in December 2002. In January 2003, the ML Committee considered the result of the DH investigation, and concluded that the manufacturer was in poor compliance with the GMP in various areas. A warning letter was issued to the manufacturer.

2. In February 2004, the manufacturer was convicted for sale of an unregistered medicine to an ASP and was fined \$3,000. In July 2005, the manufacturer was again convicted for supply of DDs on two occasions to an unauthorised person, and was fined \$10,000.

3. In the annual routine inspections of the manufacturer's premises conducted during the period January 2005 to January 2009, the DH found in each inspection 12 to 39 non-conformities. The last follow-up inspection was conducted in March 2009, a few days before a medicine incident relating to the manufacturer (at Appendix C) occurred.

#### *Audit comments*

4. Audit is concerned that, despite the poor performance of the manufacturer and his previous conviction records, the DH had not conducted more frequent inspections of the manufacturer's premises.

*Source: DH records*

- (c) ***Inadequate documentation of inspection work.*** DH inspections were conducted based on a standard checklist (with columns provided for ticks against "Yes" or "No" and for "Remarks"). During inspections, the PIs ticked against the standard checklist and put down remarks (if any) for any tick on "No" items (indicating non-compliance detected). There was no documented assessment of the impact as a result of the non-compliance. The PIs would not write down on the inspection reports details of records/medicines that had been selected for examination during inspections. Supporting documents to explain the non-compliance were not always available. Given the medicine incidents in

early 2009, the DH needs to strengthen the inspection procedures and document the work done.

3.11 In the pharmaceutical trade, many of the local manufacturers are connected with one another. For example, five GMP manufacturers were related companies (Note 33) which together took up a significant share of the pharmaceutical market. Besides, one manufacturer was very often the production contractor to one or more of the other manufacturers. **Given such a close connection among manufacturers, the impact of any inadequacies in DH inspections could be significant.**

3.12 In May 2009, the Task Force (see para. 1.14) commissioned an overseas consultant to study the GMP system in Hong Kong and, taking into account overseas practices, to recommend enhancement measures to be adopted by the pharmaceutical industry and the DH. The consultant's recommendations, which had been discussed by the Board in August 2009, were considered by the Review Committee in October 2009.

*Audit recommendations*

3.13 **The fact that many of the medicine incidents in early 2009 related to manufacturers indicates that the DH needs to step up its efforts to improve the effectiveness of its inspections of manufacturers' premises.**

3.14 **Audit has recommended that the Director of Health should:**

- (a) **uphold the DH efforts in conducting surprise inspections of manufacturers' premises;**
- (b) **for manufacturing processes that have been outsourced to contractors outside Hong Kong, consider conducting inspections of the contractors' premises; and**
- (c) **improve the effectiveness and quality of DH inspections, including the conduct of more frequent inspections (particularly on manufacturers with conviction records or poor performance) and adequate documentation of inspection work, taking into account the consultant's recommendations on the GMP system in Hong Kong.**

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**Note 33:** *Based on a company search in April 2009, it was found that the five manufacturers were related as they had largely the same directors.*

## Response from the Administration

- 3.15 The **Director of Health** welcomes the audit recommendations. He has said that:
- (a) the DH will continue to conduct surprise inspections of local manufacturers' premises. The DH will also consider conducting inspections of outsourced contractors' premises outside Hong Kong;
  - (b) compliance with the GMP is a licensing condition. The GMP is a set of guidelines for manufacturers to maintain a quality assurance system in ensuring that the medicines they produce are safe and of good quality. GMP inspections aim to ensure that the quality assurance system is in place and the manufacturer complies with the GMP guidelines. The PIs would give advice to the manufacturer for corrective and preventive measures on areas of non-compliance;
  - (c) to improve the quality and effectiveness of inspections, the DH will implement the recommendations of the Review Committee when they are made; and
  - (d) as regards Audit's concern that routine inspection of manufacturers' premises once a year is not sufficient and that there should be more frequent inspections, the DH considers that this has already been done as the DH conducts follow-up inspections when irregularities are identified in the annual routine inspections (as illustrated in Case 2 in para. 3.10(b)).

## Inspection of wholesalers' and importers/exporters' licensed premises

3.16 There are around 1,100 traders licensed to handle imports/exports and wholesale of medicines in Hong Kong. I/Es handle the import and export of medicines not classified as poisons under the PPO, while wholesalers handle the import and export of poisons and non-poisons, as well as the wholesaling of poisons.

3.17 General licensing conditions for wholesalers and I/Es include the suitability of the premises and the adequacy of knowledge of the person-in-charge in the pharmaceutical trade. Additional licensing requirements for wholesalers include proper record keeping of transactions of Part I poisons, and restriction of sale of poisons to authorised persons only.

3.18 If a wholesaler or an I/E fails to comply with the licensing conditions or has been convicted of an offence, the Pharmacy and Poisons (Wholesale Licences and Registration of Importers & Exporters) Committee of the Board (the WIE Committee) may revoke or suspend the licence for such period as it thinks fit. Similar to MLs, a WPL or a licence for I/E is valid for one year and is renewed annually.



3.19 Wholesalers and I/Es are monitored by means of **surprise** routine inspections. Routine inspections usually last for a few hours to one day and are conducted by one to two PIs. During inspections, transaction records with the relevant supporting documents, storage conditions of the premises, and the labelling of the medicines are checked. Before April 2009, no medicine samples were taken from wholesalers' and I/Es' premises during routine inspections. Starting from April 2009, the DH buys samples from wholesalers for testing by the Government Laboratory (GL). Such samples are also used for post-registration monitoring by the DH Pharmaceuticals Registration Section.

### Audit observations and recommendation

#### *Need to conduct more frequent routine inspections*

3.20 An analysis of DH inspection records indicated that for the year ended 30 June 2009, the DH had only inspected 512 (61%) of 842 wholesalers' premises and 121 (53%) of 227 I/Es' premises (Note 34). Table 1 shows an ageing analysis of the remaining 330 wholesalers' and 106 I/Es' premises which had **not** been inspected for over one year.

**Table 1**  
**Number of premises not inspected by DH**  
**(30 June 2009)**

Period not inspected	Wholesaler	I/E
Over 1 year to < 2 years	267	87
2 years to < 3 years	39	12
3 years to < 4 years	16	3
4 years to < 5 years	3	4
5 years and more	5	0
<b>Total</b>	<b>330</b>	<b>106</b>

*Source: DH records*

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**Note 34:** *During a year, the same premises could be inspected repeatedly. The DH had conducted 753 and 178 inspections of the wholesalers' and I/Es' premises respectively for the year ended 30 June 2009.*

3.21 The position in Table 1 is not satisfactory. In particular, Audit noted that some wholesalers with convictions or poor performance had not been inspected more frequently. Case 3 is an example.

### Case 3

#### DH inspection of a wholesaler's premises

##### *Case particulars*

1. Acting on a complaint, in December 2003, the DH inspected a wholesaler's premises and found that suspected unregistered medicines were kept in the storeroom, and a certain quantity of suspected Part I poisons were also kept in an unlicensed warehouse next to the premises. In March 2005, the wholesaler was convicted for possession of Part I poisons and unregistered medicines for sale or distribution, and was fined \$10,000. In April 2005, the WIE Committee issued a warning letter against him.

2. In July 2006, based on the GL test result of a sample obtained from a market surveillance, the DH found that the wholesaler was selling an unregistered pCm containing western medicine ingredients. He was again convicted for possession of unregistered medicines for sale or distribution and was fined \$8,000 in November 2007. In January 2008, the WIE Committee again issued a warning letter against him.

3. Since its last routine inspection in February 2006, up to the end of August 2009, the DH had not conducted any further routine inspections of the wholesaler's premises. It had only conducted inspection once in 2006, and twice in 2007 in relation to applications submitted by the wholesaler for changes of licensing particulars (such as change of person-in-charge of poisons). The scope of such inspections was generally limited.

##### *Audit comments*

4. Given the wholesaler's past conviction records, it is unsatisfactory that the DH had not conducted any routine inspection of the wholesaler's premises **for more than three years** (i.e. February 2006 to August 2009).

Source: DH records

3.22 In addition, Audit noted that up to March 2009, the DH had not conducted routine inspections of two wholesalers (who were related to two medicine incidents at Appendix C) for about two years. The last routine inspections were conducted in November 2006 and June 2007 respectively (Note 35). The two wholesalers' premises were only inspected during the investigations as a result of the 2009 medicine incidents.

*Thoroughness of inspections is questionable*

3.23 In each routine inspection, the PIs would select some medicines to check their expiry dates, registration numbers, label information, etc. An examination of the 2008 inspection reports revealed that most of the inspection results were satisfactory and no major non-compliance was found. Case 4, however, reflected that the thoroughness of the routine inspections was questionable.

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**Note 35:** *Nonetheless, due to changes of licensing particulars, the DH inspected one wholesaler's premises in November 2007 and the other wholesaler's premises in August 2007 and July 2008. However, such inspections were generally limited in scope.*

## Case 4

### Medicine with unregistered sales pack not detected

#### *Case particulars*

1. In April 2008, during a routine inspection of a wholesaler's premises, the DH selected medicine samples for checking their expiry date, registration number, etc. No irregularities were found. There was then no procedure for the PIs to cross-check the medicine samples against the medicine registration particulars kept by the DH. As a result, the DH was not aware that the sales pack of one medicine sample was unregistered.

2. In April 2009, following a media enquiry, the DH investigated and found that the sales packs for five medicines (one of which had been examined in the 2008 inspection) were unregistered, two of which also carried unregistered medical indications. On 7 April 2009, the DH instructed the wholesaler (who was related to one medicine incident at Appendix C) to recall them. The DH investigation found that the wholesaler had adopted the unregistered sales packs since mid-2007, but had not submitted the changes of registered particulars to the DH for approval.

#### *Audit comments*

3. In a routine inspection of a wholesaler's premises, apart from checking the storage conditions of medicines, the DH should also check for any evidence of possible offences (such as illegal sales, improper record keeping and possession of unregistered medicines). The DH inspection conducted in 2008 was not thorough enough as it failed to detect the unregistered sales pack. Nonetheless, it is pleasing to note that since April 2009, the DH has collected samples during inspections of wholesalers' premises for checking against the medicine registration particulars kept by the DH (see para. 3.19).

*Source: DH records*

#### *Audit recommendation*

3.24 **The fact that many of the medicine incidents in early 2009 related to wholesalers indicates that the DH needs to step up its efforts to conduct more frequent and thorough inspections of wholesalers, as well as I/Es (who are subject to similar regulatory controls).**

3.25 **Audit has recommended that the Director of Health should improve the effectiveness and quality of DH inspections of wholesalers' and I/Es' premises, including the conduct of more frequent and more comprehensive inspections (particularly on wholesalers with higher risk).**

### **Response from the Administration**

3.26 The **Director of Health** welcomes the audit recommendation. He has said that since April 2009, with special deployment of 10 temporary PIs, extra rounds of DH inspections have been conducted against selected wholesalers and I/Es based on risk assessments. The DH will review the current inspection strategy and make improvement measures when necessary.

### **Inspection of authorised and listed sellers of poisons**

3.27 ASPs can sell poisons (both Part I and Part II) while LSPs can only sell Part II poisons (see Note 3 to para. 1.7). The Board will issue an ASP licence if it is satisfied that an applicant is a fit and proper person and the premises are suitable to conduct the retail sale of poisons. Licensing requirements also include proper supervision of sale of poisons by a registered pharmacist. The pharmacist's name, his certificate of registration and notice of his attendance hours must be displayed in a conspicuous location inside the ASP. Other requirements include full adherence to the Code of Practice for ASP (issued by the Board) in respect of procurement, storage, sale and supply, and record keeping for transactions of medicines and poisons. The Pharmacy and Poisons (Listed Sellers of Poisons) Committee of the Board (the LSP Committee) issues licences to LSPs on the basis of the suitability of the premises and knowledge of the person-in-charge of the trade.

3.28 For both ASPs and LSPs, **surprise inspections** are conducted. Both ASPs and LSPs are inspected twice a year on average. Inspections cover compliance with regulations on the sale, storage and proper labelling of medicines and, in the case of ASPs, records of sales and physical stock of poisons.

### **Audit observations and recommendations**

#### ***Need to monitor illegal sales of medicines by unlicensed retail outlets***

3.29 The DH enforcement work mainly focuses on licensed retailers (ASPs and LSPs). The PIs seldom conduct searches for unlicensed retail outlets except when the DH receives complaints from the public or referrals from other government departments or organisations (e.g. the Police, the C&ED and the Hospital Authority (HA)).

3.30 On a number of days during March to August 2009, Audit conducted test purchases in mainly two districts, namely Tai Po and Mong Kok (in the vicinity of the MTR Tai Po Market Station and the MTR Mong Kok East Station), and was successful in test purchases of Part II poisons (Note 36) in 17 unlicensed retail shops (details of the 17 retail shops had been separately provided to the DH in April to August 2009). Of these 17 unlicensed retail shops, 4 were former LSPs who had been removed from the LSP list by the Board (Note 37), and 4 were applying for ASP/LSP licences at the time of purchases, but had not yet been approved. **Audit is concerned about the improper sale of Part II poisons by retail shops not registered with the Board as ASPs/LSPs.**

3.31 **Audit considers that the DH needs to step up its regulatory controls to prevent illegal sales of medicines by unlicensed retailers. These include, for example, imposing a requirement for ASPs/LSPs to display their licences at the entrance of their retail shops.** The DH should also consider conducting more publicity programmes to enhance the public's knowledge of medicines (e.g. to alert the public to the dangers of taking unregistered and counterfeit medicines, and to buy medicines only from reliable sources). To effectively deter improper retail sale of Part II poisons by shops which had been removed from the LSP list, the DH may also wish to explore additional measures such as publication on the DH website of the removal of an LSP, and the conduct of surprise inspections and test purchases.

#### *Enhancement of quality of routine inspections*

3.32 In 2007 and 2008, the DH carried out 991 and 1,023 routine inspections of ASPs, and 6,296 and 6,572 inspections of LSPs. A scrutiny of the DH routine inspection reports revealed that the inspection results were generally satisfactory and no major non-compliance was found. However, in 2007 and 2008, there were 50 and 60 convictions of ASPs, and 8 and 6 convictions of LSPs, respectively (see Table 5 in para. 5.4 and para. 5.5). An analysis indicates that nearly all of the convicted cases had resulted from investigations prompted by complaints or referrals, and joint operations with the Police (i.e. from sources other than DH routine inspections). For example, in 2008, only one of 60 convicted ASP cases was identified through DH routine inspections.

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**Note 36:** *Section 23 of the PPO states that no person shall have in his possession any Part I poison otherwise than in accordance with the provisions of the PPO. There is no similar provision for prohibiting the possession of Part II poisons. Therefore, Audit could only conduct test purchases of Part II poisons.*

**Note 37:** *In 2008 and the first 6 months of 2009, the Board removed the names of 7 LSPs from the list of LSPs (see Table 6 in para. 5.7), considering that they were not fit to continue the retail business of Part II poisons due to convictions. In June 2009, Audit conducted test purchases of Part II poisons in 5 of these former LSPs, and was successful in 4 of them, which meant that these 4 former LSPs were continuing the retail sale of Part II poisons.*

3.33 In March 2009, Audit staff attended the DH routine inspections of one ASP and one LSP as an observer (see Appendices F and G). Whilst DH records indicated that past inspection results of these two retailers were satisfactory, the DH made various observations in the two routine inspections accompanied by Audit staff, thus casting doubt on the quality of previous inspections. The DH needs to review how the quality of its routine inspections of ASPs and LSPs can be enhanced.

*Need to inspect convicted ASPs more frequently*

3.34 ASPs with conviction records warrant close monitoring. From an examination of the DH inspection records, Audit however found that the DH had not always inspected convicted ASPs more frequently. The average rate of inspecting twice a year for such ASPs was not always achieved. Two examples are shown at Appendix H.

*Audit recommendations*

3.35 **Audit has recommended that the Director of Health should:**

- (a) **take steps to strengthen the DH regulatory controls to prevent illegal sales of medicines, including, for example, inspecting convicted ASPs more frequently;**
- (b) **conduct more publicity programmes to enhance the public's knowledge of medicines;**
- (c) **explore the desirability of imposing a requirement for ASPs/LSPs to display their licences at the entrance of their retail shops;**
- (d) **explore additional measures, such as publication on the DH website of the removal of retailers from the LSP list, and the conduct of surprise inspections and test purchases, to effectively deter improper retail sale of Part II poisons by former LSPs; and**
- (e) **review how the quality of the DH routine inspections of ASPs and LSPs can be enhanced.**

## Response from the Administration

3.36 The **Director of Health** welcomes the audit recommendations and will take steps to implement various improvement measures. He has said that:

- (a) the purpose of routine inspections is to ensure compliance with professional standards. Discovery of fraud is not the objective. Thus, the audit observations that the vast majority of conviction cases were not detected during routine inspections do not have any bearing on the quality and effectiveness of such inspections; and
- (b) Audit's doubt on the quality of routine inspections was generalised from its observations on the routine inspections of one ASP and one LSP (see paras. 3.32 and 3.33). The major irregularities Audit noted from the attendance at the DH inspection of an ASP's premises related to the non-detection of some improperly completed prescriptions (see para. 3 of Appendix F).

## Market surveillance

3.37 As part of the safety and quality monitoring programmes of medicines, the DH collects samples of medicines and non-pharmaceutical products from the market for testing. Products under market surveillance include registered medicines, virility and slimming products, pCms, and other products purported to treat diseases. The main objectives of market surveillance are to ensure that the medicines or products being sold in Hong Kong are safe and of good quality, and to help identify whether the products contain harmful substances and undeclared potent western medicines.

3.38 In 2008 and 2009 (up to 30 June), the DH collected 2,391 samples and 1,462 samples respectively for analysis. Details are as follows:

Type of product	No. of samples	
	2008	2009 (up to 30 June)
(a) Western medicines	30	304
(b) Non-pharmaceutical products (e.g. virility and slimming products, and pCms)	2,361	1,158
<b>Total</b>	<b>2,391</b>	<b>1,462</b>



## Audit observations and recommendation

3.39 Audit notes that the DH has adopted the following strategy in market surveillance:

- (a) with a series of incidents in 2008 involving undeclared western medicines found in virility and slimming products, the DH has stepped up its efforts to identify the problematic products. As a result, the majority of the 2,361 samples collected in 2008 related to virility and slimming products; and
- (b) it has also implemented a system, based on risk assessments, to determine the priorities of referring samples collected to the GL for testing. Medicines and products relating to complaints and incident reports are accorded high priorities. Priorities have also been given to virility and slimming products, medicines/products for diabetics, and steroid-containing products.

3.40 Audit notes that whilst the DH has a market surveillance strategy in place, it has not documented the strategy. **As a good management practice, Audit has recommended that the Director of Health should document the DH market surveillance strategy, and regularly review and update it to meet changing circumstances.**

## Response from the Administration

3.41 The **Director of Health** agrees with the audit recommendation. He has said that the existing DH market surveillance strategy, which was disseminated to staff via electronic mails, will be formalised in an integrated manner and be reviewed regularly.

## Test purchases

3.42 The DH conducts test purchases from retailers to detect illegal sale of medicines at the street level. There are two types of test purchases, namely routine test purchases and controlled test purchases. In 2008, the DH had conducted 4,495 test purchases, 60 of which were successful (e.g. the DH was able to purchase some "prescription-only" medicines without a prescription — Note 38).

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**Note 38:** *"Prescription-only" medicines include Part I 3rd Schedule poisons, antibiotics and DDs. They must be sold or supplied with the authority of a prescription from a doctor or dentist.*

3.43 Routine test purchases are performed by casual workers acting as customers to purchase some commonly abused medicines from retailers (mainly ASPs). On the day of operation, the casual workers receive instructions from the supervising PI (on details such as the district to be surveyed and the medicine to be test purchased). After an operation, the casual workers record results of the test purchases in a standard "Test Purchase Daily Report". A monthly summary report will be prepared for submission to the Senior Pharmacist for follow-up actions.

3.44 Controlled test purchases are conducted at target retailers which have been suspected of involvement in illegal sale of medicines. Such controlled test purchases are mostly conducted in response to complaints or as a follow-up of successful routine test purchases. Repeated controlled test purchases are, however, seldom conducted.

### **Audit observations and recommendations**

3.45 From an examination of the DH records and Audit attendance as an observer of the DH routine test purchases, Audit had the following observations:

- (a) routine test purchases were all carried out during office hours on weekdays. This was not satisfactory as illegal sale of Part I poisons might be more prevalent during weekends and night-time when the ASPs were generally not manned by registered pharmacists; and
- (b) four casual workers responsible for conducting test purchases were assigned to purchase the same medicines (e.g. a particular brand of "prescription-only" medicine) for a number of months.

3.46 **Audit has recommended that the Director of Health should review and improve the existing mode of conducting test purchases. In particular, consideration should be given to:**

- (a) **conducting test purchases during weekends and night-time; and**
- (b) **purchasing different medicines (based on risk assessment) at different times and different places.**

### **Response from the Administration**

3.47 The **Director of Health** welcomes the audit recommendations.

## **PART 4: MEDICINE TESTING, RECALLS AND PUBLIC ALERTS**

4.1 This PART examines the DH procedures on medicine testing, monitoring of medicine recalls and issuing of public alerts.

### **Monitoring the safety, efficacy and quality of medicines**

#### *Pre-market control*

4.2 Under the PPO, medicines must be registered with the Board before sale in Hong Kong. When the medicine's safety, efficacy and quality have been proved to the satisfaction of the Board, the medicine can be registered. To this end, a Hong Kong registration certificate bearing the name of the medicine and the registration number will be issued. The certificate is valid for five years and renewable on expiration.

#### *Post-market control*

4.3 The DH collects medicine samples from various sources for testing by the GL (Note 39). Such sources include:

- (a) ***Retail outlets and dealers' premises.*** The DH obtains medicine samples from the market (see para. 3.37), and from manufacturers and wholesalers (during inspections of their premises); and
- (b) ***Follow-up on complaints and referrals.*** The DH collects samples in following up on public complaints and referrals (e.g. from the HA) on quality and safety problems of medicines.

4.4 The samples collected will be passed to the GL for testing. Based on the GL test results, the DH determines whether it needs to take enforcement action. Where necessary (e.g. when the medicine poses a health risk to the public), the DH will require the wholesaler or manufacturer concerned to recall the medicine from the market. The DH may also issue notices to alert the public.

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**Note 39:** *The GL conducts mainly chemical tests of the samples referred to it by the DH. The tests commonly include qualitative and quantitative analyses of the samples. In the case of sterile medicines, it also conducts sterility tests.*

*Audit examination*

4.5 Audit examined the following issues in this PART:

- (a) collection of medicine samples for testing (paras. 4.6 to 4.17); and
- (b) medicine recalls and public alerts (paras. 4.18 to 4.30).

**Collection of medicine samples for testing**

4.6 In 2008 and 2009 (up to 30 June), the DH delivered 4,902 and 2,698 samples respectively to the GL for testing, as detailed in Table 2.

**Table 2**  
**Samples collected from various sources for GL testing**  
**(2008 to June 2009)**

Source	No. of samples	
	2008	2009 (up to 30 June)
(a) Applications for medicine registration (see paras. 4.2 and 4.9)	1,882	0
(b) Manufacturers' premises	282	871
(c) Market surveillance (see para. 3.38)	2,391	1,462
(d) Wholesalers' premises	0	175
(e) Investigations based on complaints or referrals	347	190
<b>Total</b>	<b>4,902</b>	<b>2,698</b>

*Source: DH records*

## Audit observations and recommendations

### *Samples taken from different sources*

4.7 The DH has not set any targets on the number of medicine/product samples to be taken from different sources each year. However, it had agreed with the GL on an estimated annual test workload of 4,500 samples (Note 40).

4.8 On the basis of a total of 2,698 samples tested for the first six months of 2009 (see Table 2), the sample test requirement this year may exceed the agreed test workload of 4,500 samples. **Audit considers that the DH needs to review its sample test requirement and, if necessary, liaise with the GL with a view to increasing the agreed test workload.**

### *Testing of samples collected for medicine registration*

4.9 Before 2 January 2009, the Board used to require applicants to submit medicine samples for testing by the GL before approving their medicine registration. Since 2 January 2009, the DH has streamlined the procedures by removing the GL test requirement. As informed by the DH, this would shorten the registration lead time and was more in line with the procedures adopted in other national health authorities. Furthermore, the DH considered that, with the adoption of the streamlined procedures, a significant percentage of the GL workload quota could be released for other uses.

4.10 Audit noted that in 2008, of 1,882 samples referred by the DH to the GL for pre-registration tests, 50 (2.7%) samples had failed the tests. **As there may be risks associated with the adoption of the streamlined procedures, Audit considers that the DH needs to conduct a post-implementation review to assess whether the streamlined procedures are effective.**

### *Testing of samples collected from manufacturers' premises*

4.11 In 2008, the DH sent 282 samples collected from manufacturers' premises during inspections to the GL for testing (see para. 3.5). A workflow analysis showed that the DH had not promptly delivered the 282 samples to the GL for testing, and had not promptly collected the GL test results for follow-up, with details as follows:

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**Note 40:** *These comprise 2,100 samples for western medicines and 2,400 samples for virility and slimming products, pCms, and other products purported to treat diseases.*

- (a) ***Samples not promptly delivered to GL for testing.*** The samples collected from the manufacturers' premises were locked up by the DH in cabinets in the office of the Public Health Laboratory Centre. There was, on average, a time lag of 168 days (5.5 months) before samples were delivered to the GL for testing (see analysis in Table 3). In one extreme case, the time lag was 303 days (almost 10 months). Audit noted that samples taken from the premises of two GMP manufacturers (who were related to two medicine incidents at Appendix C) in December 2007 and January 2008 respectively were only sent to the GL for testing in late April 2008; and

**Table 3**  
**Time lag before samples were delivered to GL**  
**(2008)**

Time lag (days)	Number of samples involved	Percentage
251 to 303	33	12%
201 to 250	77	27%
151 to 200	71	25%
101 to 150	30	11%
51 to 100	40	14%
1 to 50	31	11%
<b>Total</b>	<b>282</b>	<b>100%</b>

*Source: Audit analysis of DH records*

*Remarks: The DH normally arranged a workman to deliver the samples under seal to the GL. The samples were usually sent in batches. In 2008, samples in 10 batches were delivered to the GL.*

- (b) ***GL test results not promptly collected.*** There was, on average, a time lag of 51 days (almost 2 months) before test results from the GL were collected (see analysis in Table 4). In one extreme case, the time lag was 124 days (4 months). On 3 December 2008, the DH collected the GL test results for 8 samples taken from the premises of a GMP manufacturer (who was related to one medicine

incident at Appendix C), although the GL had in fact completed the tests in late September 2008.

**Table 4**  
**Time lag before GL test results were collected**  
**(2008)**

Time lag (days)	Number of samples involved	Percentage
101 to 124	6	2%
81 to 100	22	8%
61 to 80	72	26%
41 to 60	79	28%
21 to 40	76	27%
1 to 20	26	9%
<b>Total</b>	<b>281</b> <b>(Note)</b>	<b>100%</b>

*Source: Audit analysis of DH records*

*Note: In 2008, the DH delivered 282 samples to the GL for testing (see Table 3). Because the test for one sample was cancelled, test results were available for 281 samples only.*

*Remarks: The DH usually asked the workman to collect the GL test results (for samples previously sent) when he took new samples to the GL for testing.*

4.12 **Audit is concerned about the slow action in delivering samples to the GL and in collecting the test results.** An analysis of the 281 samples mentioned in Table 4 shows that there was, on average, a time lag of 268 days (almost 9 months) to complete a sample test (from sample collection to obtaining GL test result). In 37 (13% of 281) samples, the time lag was more than one year. The long time lag would delay any recall action and/or the issue of public alerts that might be required for any medicines found to be defective. Audit noted that in 2008, in 4 cases of failed GL tests, the DH had to urge the manufacturers to initiate recall actions. **For these 4 cases, there was a time lag of 68 to**

**427 days between sample collection and obtaining the GL test results (Note 41). Such a long time span is undesirable.**

4.13 In August 2009, the DH informed Audit that it had agreed with the GL that if there was any failed test result, the GL would inform the DH by fax without delay. The DH also said that the purpose of GL tests on medicines taken from the manufacturers' premises was to validate the results conducted by the manufacturers' laboratories, and the impact of substandard results was generally on quality and not safety. Given that such GL tests would normally involve no public health concern and did not require any issue of public alert, the DH accorded lower priorities to such GL tests. The DH would generally give higher priorities to testing those medicine samples collected from investigation and market surveillance (Note 42). Based on risk assessments, the DH had agreed with the GL on a list of products that should be accorded higher priorities in laboratory testing (e.g. virility and slimming products — see para. 3.39(b)).

4.14 In 2009, after the medicine incidents, the DH has expedited action in delivering samples to the GL for testing. For the quarter ended June 2009, the time lag was on average 26 and 9 days respectively for delivering samples to the GL and for collecting the test results. The GL had also speeded up its testing work, and took on average 14 days to complete the tests. There were occasions when the GL sent the test results to the DH by fax once the results were available. There have been great improvements overall. **Audit considers that the DH needs to, in collaboration with the GL, make sustained efforts to further improve the sample testing procedures.** In this connection, the DH may wish to explore using information technology (IT) to improve its information sharing (such as that relating to the movements of samples and dissemination of test results) with the GL.

#### *Audit recommendations*

4.15 **Audit has recommended that the Director of Health should:**

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**Note 41:** *For these 4 cases, the DH had taken 34, 14, 197 and 163 days respectively to deliver the samples to the GL. The GL had also taken 29, 117, 198 and 214 days respectively to complete the tests, and another 5, 10, 32 and 50 days respectively to inform the DH of the test results.*

**Note 42:** *Audit noted that the DH was able to deal with samples collected from investigations very promptly. For such samples, the responsible PIs usually kept the samples themselves and would personally deliver the samples to the GL within 1 to 2 days, and would follow up when the GL test reports were available. In urgent cases, the PIs might even ask the GL to send back the test reports by fax.*



*Samples taken from different sources*

- (a) review the DH's sample testing requirements each year and, if necessary, liaise with the GL with a view to increasing the agreed test workload;

*Testing of samples collected for medicine registration*

- (b) conduct a post-implementation review to assess whether the streamlined procedures are effective;

*Testing of samples collected from manufacturers' premises*

- (c) in collaboration with the Government Chemist, make sustained efforts to further improve the sample testing procedures; and
- (d) explore the feasibility of using IT to improve the DH's information sharing (such as information relating to the movements of samples and dissemination of test results) with the GL.

**Response from the Administration**

4.16 The **Director of Health** welcomes the audit recommendations. He has said that:

*Samples taken from different sources*

- (a) the DH will review with the GL on the testing workload to match with the heightened regulatory demand;

*Testing of samples collected for medicine registration*

- (b) the DH will conduct a post-implementation review to assess whether the streamlined procedures are effective;

*Testing of samples collected from manufacturers' premises*

- (c) sample testing on products from different sources is risk-based. Samples collected for investigations of complaints or medicine incidents are accorded the highest priorities. Priorities will also be given to virility and slimming products, medicines/products for diabetics, and steroid-containing products collected from

the market. For these samples, the GL will fax the test results to the DH for action as soon as they are available;

- (d) samples taken from local manufacturers and retailers (for verification purposes) are, on the other hand, given lower priorities. These samples are collected during inspections of manufacturers' premises in connection with their annual licence renewal (which are usually clustered within a few months of a year). The delivery of these samples to the GL for testing has to be spread over the year having regard to the capacity of the GL;
- (e) as mentioned in paragraph 4.14, in 2009, the DH has greatly improved the timing for sending samples to the GL by redeploying resources saved from the streamlined medicine registration procedures. The DH will make sustained efforts to streamline the sample testing procedures in collaboration with the GL; and
- (f) the DH will explore with the GL on the feasibility of using IT to monitor the movement of samples and dissemination of results.

4.17 The **Government Chemist** agrees with the audit recommendation in paragraph 4.15(a). He also agrees to liaise with the DH on the audit recommendations in paragraph 4.15(c) and (d). He has said that:

- (a) during 25 March to 2 April 2009, the DH submitted an urgent request involving 620 samples (which was about 2.5 months' normal workload of the same sample type), and the GL reported the test results within a turnaround time of 1 to 22 days (average: 9 days). This was much shorter than the normal turnaround time of around 30 days. High priority had been accorded to the exercise with the deployment of extra manpower, instruments and other resources to complete the requested analyses;
- (b) generally there are certain samples for which a longer turnaround time is necessary, e.g. verification of testing methods and purchase of reference materials. Subject to the urgency of the requests, the turnaround time for the testing can range from a few to over 100 days. In general, the GL would inform the DH immediately of the test results for urgent cases or failed samples. For other routine cases, the GL would not inform the DH for collection of individual test reports;
- (c) with the streamlined procedures adopted by the DH since 2 January 2009 (see para. 4.9), post-registration tests are accorded a much higher priority and can now be generally completed with a shorter turnaround time. This is because:
  - (i) as compared with the pre-registration tests, there are less frequent situations where further information from the manufacturers is required that are sometimes

associated with a long waiting time; and (ii) batch analysis is possible if similar product categories are submitted at the same time after market surveillance; and

- (d) regarding the audit recommendation in paragraph 4.15(d), the GL has just commenced implementing a project “Pilot Implementation of Functional Laboratory Information Management System”. It is expected that the system will have potential for inter-departmental data sharing.

## **Medicine recalls and public alerts**

4.18 The PPO requires manufacturers and wholesalers to devise and maintain a recall mechanism to enable the rapid and, as far as practicable, complete recall of any batch of a product from sale to the public in the event of the product being found to be dangerous or injurious to health. In 2008 and 2009 (up to 30 June), there were 42 and 28 medicine recalls respectively.

4.19 To assist manufacturers and wholesalers in recall actions, in 2000, the DH issued a set of recall guidelines. The guidelines provide that:

- (a) the responsibility for deciding whether a defective medicine should be recalled or not rests primarily with the manufacturer or wholesaler;
- (b) in a recall, the DH’s role is to assess the adequacy of decision made by the manufacturer/wholesaler on the recall of the product and to monitor the progress and effectiveness of the recall;
- (c) the manufacturer/wholesaler has to submit interim and final reports on the progress of recall to the DH; and
- (d) depending on circumstances, the DH may also issue an alert notice to inform the public of the medicine problem.

## **Audit observations and recommendations**

### ***Need for recall actions***

4.20 A medicine will become unregistered if its registration has not been renewed upon expiry. Under the PPRs, the sale, offer for sale, distribution or possession of unregistered medicine is an offence under the PPO. Audit noted that the DH had no procedures for requiring the manufacturers/wholesalers to recall medicines with expired registration. Audit also found from market surveys in June and July 2009 that two medicines, the registration of which had expired (one in October 2008 and one in

May 2009), were still available for sale in the market. **Audit considers that the DH needs to remind manufacturers/wholesalers to recall medicines with expired registration.**

4.21 There are no DH guidelines to assist PIs in making decisions on when they should request the manufacturers/wholesalers to take recall actions. Audit noted a case when the DH did not ask the wholesaler to recall a substandard medicine the registration of which had expired (see Case 5).

### Case 5

#### No recall action initiated

##### *Case particulars*

1. The PI had not requested the wholesaler to recall a medicine from the market, although the GL test result for the medicine of July 2008 indicated that the content of the active ingredient in the medicine had exceeded the labelled specifications by 66%.

2. In response to Audit's enquiry, in early August 2009, the PI explained that he did not do so because the registration of the medicine concerned had expired in February 2008 and the wholesaler did not renew the registration.

##### *Audit comments*

3. The DH should have urged the wholesaler to recall the medicine from the market because:

- (a) it was found to be substandard; and
- (b) it might still be available in the market if the wholesaler had not previously taken any recall action.

*Source: DH records*

4.22 As long as a wholesaler has not taken any recall action, a medicine may still be available in the market. **Audit considers that the DH needs to remind its staff of the need to request the manufacturers/wholesalers to take recall actions when defective/substandard medicines are found, even if the registration of the medicines concerned has not been renewed.**

### *Monitoring the effectiveness of recall actions*

4.23 According to the DH recall guidelines (see para. 4.19), dealers have to furnish interim and final reports to the DH on the progress of recalls. The reports have to provide details of organisations and persons to whom the medicines have been supplied, the recall rate (medicines recalled as against the total quantities supplied to the market), and the names of any non-responders.

4.24 Audit examined 30 (of 42) recall reports of 2008 (see para. 4.18) submitted by the manufacturers and wholesalers, and noted the following:

- (a) 16 (53%) recall reports provided only information on the total quantities recalled, without details of the organisations and the persons, and the total quantities supplied to them. The inadequate information would render it difficult for the DH to evaluate the effectiveness of the recall actions. However, Audit noted that the DH had not taken any follow-up actions (such as requesting additional information); and
- (b) an examination of the remaining 14 (47%) recall reports showed that although they provided details of recalls, the percentage of medicines recalled were generally very low (Note 43). Among the 14 recall reports, 4 showed medicine recall rates of less than 10%, including 2 with a recall rate of 0%. While the low recall rate could mean that most of the medicines had been sold, there is a possibility that the medicines had not been effectively recalled. The DH had not conducted inspections at retail outlets to ascertain if the medicines with low recall rates were still available in the market.

4.25 From April 2009 onwards, the DH has tightened up the procedures by requiring the PIs to complete a proforma (using a standard template) on progress of medicine recalls. The proforma has to be submitted to the Chief Pharmacist of Pharmaceutical Service for information. The PIs have to report the number of retail outlets inspected and the inspection results to assess the effectiveness of the recall actions and determine the need for issuing public alerts. **Audit welcomes the DH's initiative to tighten up the controls, and considers that the DH needs to sustain its efforts to monitor the recall actions taken by manufacturers/wholesalers.**

### *Issue of public alerts*

4.26 From time to time, the DH may issue public alerts to notify the public of medicine problems. In 2008 and 2009 (up to 30 June), the DH issued 56 and 39 public

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**Note 43:** *The medicine recall rate is calculated by dividing the total quantities recalled by the total quantities supplied to the market, multiplied by 100%.*

alerts respectively. Most of the public alerts related to unregistered products (e.g. slimming and virility products) containing undeclared western medicine ingredients, and medicines with serious side effects or with unregistered indications.

4.27 Based on an examination of all 14 manufacturers/wholesalers' recalls and 35 DH investigation cases that involved defective/substandard medicines in 2008, Audit noted that there were instances when the DH had not issued any public alerts or the public alerts were not issued promptly. Two examples are given below:

### Case 6

#### Public alert not issued

##### *Case particulars*

1. On **23 October 2008**, the European Medicines Agency (EMA) posted an announcement on its website that it recommended the suspension of the marketing authorisation for a particular medicine across the European Union. The decision was made as a result of an EMA review of the medicine after concerns were raised about its psychiatric safety. The review had found that the benefits of the medicine did not outweigh the risks of psychiatric reactions in clinical use.
2. On **24 October 2008**, the wholesaler in Hong Kong notified the DH that the medicine's marketing authorisation in Hong Kong would also be suspended and the medicine would be recalled from doctors, ASPs and hospitals.
3. In **December 2008**, the wholesaler reported to the DH that only 2,100 (15%) out of 13,900 boxes of the medicines imported could be recalled.
4. As far as could be ascertained, the DH had not issued any public alert on the medicine. There was also no record documenting why the DH had decided not to issue a public alert.

##### *Audit comments*

5. Given the EMA's concerns about the psychiatric safety of the medicine concerned and, in the absence of any documentation available to support the DH's decision of not issuing a public alert, Audit has reservation on whether the DH had made a proper response to the incident. The low recall rate of 15% further suggested that there might be patients who were not aware of the medicine problem.

Source: DH records

## Case 7

## Public alert not promptly issued

*Case particulars*

1. In **April 2008**, the HA reported to the DH that a patient being treated at the Tuen Mun Hospital for her chronic rheumatic heart disease had a history of taking a particular health product. The HA suspected that the product was adulterated with western medicine ingredients. Following a GL test, the DH found that the product contained ingredients which might cause serious side effects and should only be used under medical supervision.
2. The DH investigation could not identify the source of the product. The case was closed in September 2008. The DH did not issue any public alert. There was also no record documenting why the DH had decided not to issue a public alert.
3. In **April 2009**, the HA reported to the DH that another patient admitted to the Princess Margaret Hospital was affected by the consumption of the same product. After investigation and the GL test, the DH found in May 2009 that the product contained the ingredients mentioned in paragraph 1 above.
4. In **May 2009**, the DH issued a notice to alert the public to the product problems (one medicine incident at Appendix C is relevant).

*Audit comments*

5. In the absence of any documentation available to support the DH's decision of not issuing a public alert in 2008, Audit has reservation on whether the DH had made a proper response to the incident mentioned in paragraph 1 above.

Source: DH records

4.28 From April 2009 onwards, the DH has required its staff to fill in a proforma for a preliminary assessment on whether public alerts should be issued, taking into account factors such as public risks and the availability of the medicine in the retail market. Audit welcomes the tightened measures.

*Audit recommendations*

- 4.29 **Audit has recommended that the Director of Health should:**
- (a) **remind the DH staff of the need to request the manufacturers/wholesalers to take recall actions when defective/substandard medicines are found, even if the registration of the medicines concerned has not been renewed;**
  - (b) **remind manufacturers/wholesalers to recall medicines with expired registration; and**
  - (c) **sustain the DH's enhanced efforts to monitor recall actions taken by manufacturers/wholesalers.**

**Response from the Administration**

4.30 The **Director of Health** welcomes the audit recommendations. He has said that public alert and the reporting of drug adverse reaction are part and parcel of the post-market actions of pharmacovigilance (see Note 9 to para. 1.20(a)). To enhance the pharmacovigilance system, the DH has commissioned an overseas consultant to conduct a review (see para. 1.14). The consultant's recommendations are being considered by the Review Committee.



## **PART 5: LICENCE-REFUSAL CRITERIA, PROSECUTIONS AND DISCIPLINARY ACTIONS**

5.1 This PART examines the Board/DH's licence-refusal criteria, prosecutions and disciplinary actions on dealers.

### **Licence-refusal criteria**

5.2 All dealers in the medicine supply chain are subject to licensing control (see para. 1.7). Once they have obtained the relevant licences, they may apply for renewal of their licences annually. Section 29 of the PPO has provided that the Board may make regulations (subject to the approval of LegCo) to govern the licensing of the dealers. The following PPO and PPR provisions are also relevant:

- **ASP:** the Board shall **not** register premises of an ASP unless it is satisfied that the ASP is a **fit and proper person** to conduct the retail sale of poisons;
- **LSP:** the Board may direct its Secretary not to enter in, or to remove from, the **list of LSPs** (Note 44) the name of any person who in its opinion is, for any sufficient reason relating to him personally or to his premises, **not fit** to be on the list;
- **Manufacturer:** the ML Committee may revoke the licence or suspend the licence for such period as it thinks fit, if in its opinion the licensee has failed to comply with the licensing conditions or with the PPR;
- **Wholesaler:** the issue of a WPL shall be **at the discretion of the WIE Committee**; and
- **I/E:** the WIE Committee may grant or refuse any application for registration as an I/E **as it may deem fit.**

5.3 The Board and its committees have laid down the following criteria for refusing a licence application (**licence-refusal criteria**):

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**Note 44:** *Under section 25(1) of the PPO, the Board has to maintain a list of LSPs which contains the names of persons who are entitled to conduct the retail sale of Part II poisons.*

**ASP**

The Board will refuse an application for registration or renewal of registration of an ASP's premises if the applicant or his personnel has been convicted of **two or more offences within the last 3 years, all of which involving psychotropic drugs, zopiclone or sale of cough medicines.**

***Manufacturer, wholesaler, I/E or LSP***

- (a) Before 13 May 2009, the relevant committees (Note 45) would refuse a licence application if:
  - (i) two convictions had been registered against any person concerned under **the PPO, the ABO or the DDO** within the last 3 years; or
  - (ii) any person concerned had been convicted of **an offence of any drug of abuse** within the last 3 years.
  
- (b) Effective from 13 May 2009, the relevant committees will refuse a licence application if:
  - (i) **two drug-related convictions** have been registered against any person involved in the applicant company within the last 3 years; or
  - (ii) **one conviction related to any drug of abuse, counterfeit drug, or unregistered medicine** has been registered against any person involved in the applicant company within the last 3 years.

## **Prosecutions and disciplinary actions**

### ***Prosecutions***

5.4 When an offence is detected, the DH will seek advice from the Department of Justice (DoJ) on whether the case should be prosecuted. When legal advice supports prosecution, the DH will prepare the case to be referred to court. As a result of prosecutions, dealers may be convicted. If the DoJ does not recommend prosecution, the DH

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**Note 45:** *Relevant committees refer to the ML Committee, the WIE Committee and the LSP Committee. Each of these committees comprises the DH Chief Pharmacist (as the Chairman) and three registered pharmacists outside the Government.*

may issue warning letters to the dealers and/or their personnel for the misconduct. Table 5 shows the numbers of convictions since 2006.

**Table 5**  
**Convictions as a result of prosecutions**  
**(2006 to June 2009)**

Dealer	Number of cases			
	2006	2007	2008	2009 (up to 30 June)
Manufacturer	0	0	0	2
Wholesaler	4	4	3	2
I/E	2	1	1	1
ASP	30	50	60	17
LSP	10	8	6	1
Others (e.g. unlicensed dealers)	22	23	33	14
<b>Total</b>	<b>68</b>	<b>86</b>	<b>103</b>	<b>37</b>

Source: DH records

5.5 Many of the convictions related to the possession of unregistered medicines, the possession of Part I poisons, the sale of Part I poisons without the supervision of a registered pharmacist, and the illegal sale of “prescription-only” medicines.

#### ***Disciplinary actions***

5.6 Disciplinary matters concerning **manufacturers, wholesalers and I/Es** are handled by the ML Committee and the WIE Committee under the Board (see Note 45 to para. 5.3). They may revoke the dealers’ licences or suspend the licences for a specified period. Alleged misconduct involving **ASPs** is subject to inquiry by a Disciplinary

Committee (Note 46) appointed by the Board. Disciplinary sanctions may range from written warning to disqualification from being an ASP for a specified period of time (i.e. suspension of licence). For minor infringement, the Board may direct an interview to be conducted and a verbal caution to be given to the ASP or pharmacist concerned. In the case of LSPs, no disciplinary inquiry will be held. The LSP Committee will only consider and approve applications for LSP. If an LSP is convicted of any offence under the PPO, the ABO or the DDO, his case will be submitted to the Board for consideration. The Board may direct the removal of the LSP from the list of LSPs (see second inset in para. 5.2).

5.7 Table 6 shows a summary of the disciplinary actions taken against different types of dealers from 2006 to June 2009. Disciplinary actions for minor infringement, including the issue of written warning and verbal caution, are not included.

**Table 6**

**Disciplinary actions taken  
(2006 to June 2009)**

Dealer	Licence revoked/ Removal from list					Licence suspended				
	2006	2007	2008	2009 (up to June)	Total	2006	2007	2008	2009 (up to June)	Total
Manufacturer	0	0	0	0	0	0	0	0	2	2
Wholesaler	0	0	1	0	1	1	0	1	0	2
I/E	0	0	0	0	0	0	0	0	0	0
ASP	0	0	0	0	0	16	9	15	8	48
LSP	8	2	5	2	17	0	0	0	0	0
<b>Total</b>	<b>8</b>	<b>2</b>	<b>6</b>	<b>2</b>	<b>18</b>	<b>17</b>	<b>9</b>	<b>16</b>	<b>10</b>	<b>52</b>

Source: DH records

**Note 46:** *The Disciplinary Committee is chaired by the Deputy Director of the DH. It also contains two registered pharmacists (not being public officers) nominated by the Pharmaceutical Society of Hong Kong and a legal advisor.*

5.8 Table 6 shows that from 2006 to June 2009, most of the disciplinary actions related to the removal of LSPs from the LSP list, and the suspension of ASPs from business for a certain period of time.

### *Audit examination*

5.9 Audit examined the following issues in this PART:

- (a) enforcement of disciplinary actions (paras. 5.10 to 5.20);
- (b) effectiveness of licence-refusal criteria and disciplinary actions (paras. 5.21 to 5.32); and
- (c) instigation of disciplinary actions (paras. 5.33 to 5.38).

### **Enforcement of disciplinary actions**

5.10 As shown in Table 6, one wholesaler's licence was revoked in 2008. In October 2008, the WIE Committee revoked the WPL of the wholesaler (Dealer 3 — see para. 2.28(e)) with immediate effect on the grounds that one of his employees had been convicted of various charges at the wholesaler's registered premises and at another unregistered premises. Such charges included possession of Part I poisons, unregistered medicines, antibiotics, and counterfeit goods (Note 47). The employee was fined \$7,000 and sentenced to 80-day imprisonment suspended for 2 years.

5.11 Table 6 also shows that the Board had removed from the list of LSPs the names of 5 LSPs in 2008 and 2 LSPs in the first 6 months of 2009, considering that they were not fit to continue the retail business of Part II poisons due to convictions.

### **Audit observations and recommendations**

#### *Revocation/removal of licences*

5.12 As mentioned in paragraph 3.30, Audit found that 4 former LSPs were still continuing the retail sale of Part II poisons after their removal from the LSP list. Audit also suspected that subsequent to the WPL revocation, Dealer 3 was still involved in the poisons business, as detailed below.

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**Note 47:** *Based on DH records, Dealer 3 first obtained his WPL in February 2006. His person-in-charge of poisons (who was also one of the two directors of the company) was convicted in 1997 for possession of unregistered medicines and the conduct of medicine business as an importer without a licence. In 2008, the DH directed Dealer 3 to recall two unregistered medicines from the market, and issued a warning letter against him.*

**Case 8**

**Dealer 3**

1. Dealer 3's WPL was revoked in October 2008. On the day following the licence revocation, the DH visited Dealer 3's premises. Dealer 3 showed to the DH the poisons records for transferring all the poisons he held to another licensed dealer. The DH then inspected the premises and found no poison kept in the premises.

2. The facts below, however, suggest that Dealer 3 might still have been involved in the poisons business after the revocation of the WPL.

3. **Fact 1.** Based on import/export declarations made by Dealer 3 under the I&E Ordinance (see Note 27 to para. 2.27), he had imported cough medicines in December 2008 and re-exported them to another country in January 2009, as detailed below:

<p>Shipment in December 2008</p>	<p><b>Per import declaration:</b></p> <ul style="list-style-type: none"> <li>• 100 cartons of cough and cold medicated syrup (72 bottles per carton)</li> <li>• 100 cartons of cough suppressant (48 bottles per carton)</li> </ul>
<p>Shipment in January 2009</p>	<p><b>Per export declaration:</b></p> <ul style="list-style-type: none"> <li>• 100 cartons of cough and cold medicated syrup (72 bottles per carton)</li> <li>• 100 cartons of cough suppressant (48 bottles per carton)</li> </ul>

*Source: Import/export information lodged by Dealer 3 with the C&ED*

4. Audit found that the above 2 transactions (involving 2 declarations) were related to 2 ILs and 2 ELs applied by a manager of Dealer 3 in the name of another dealer (Dealer 4) who, based on DH routine inspection reports, had no transactions in wholesale of poisons in 2008 and 2009 (up to August 2009). Based on DH records, there was no evidence that the manager of Dealer 3 was also a staff of Dealer 4.

5. **Fact 2.** In September 2009, the DH received a letter from Dealer 3 enquiring whether he could ask another dealer to re-export 29 carton boxes of medicines he had imported for re-export purposes under an IL issued in June 2008. He claimed that because his WPL was revoked in October 2008 at short notice, he could not arrange in time for the re-export of the imported medicines. Based on the supporting documents attached to the IL, the imported medicines belonged to Part I poisons and were unregistered.

6. While the C&ED was still investigating into Dealer 3's business (see para. 2.28(e)), the DH also conducted an investigation by visiting Dealer 3's premises in September 2009. During its investigation, the DH seized 29 carton boxes of medicines (Note 1) on the grounds that Dealer 3 was suspected of illegally possessing Part I poisons. The 29 cartons of medicines were seized from the premises of Dealer 5 (who was related to Dealer 3 — see para. 5.16). On the same day, the DH reported the case to the Police and referred samples of the medicines seized to the GL for testing.

7. **Fact 3.** Audit further found in September 2009 that although Dealer 3 had his WPL revoked in October 2008, he continued to display for sale on his website products which had the same product names and similar sales packs as those seized (see para. 6 above) and which, according to DH records, contained Part I poisons and were unregistered. The case had been referred to the DH for follow-up.

#### ***Audit comments***

8. Whilst Facts 1 to 3 above are not conclusive evidence to show that Dealer 3 was still involved in the poisons business after revocation of his WPL in October 2008, they warrant further investigation. For example, for Fact 1, the DH may wish to investigate, in consultation with the C&ED, into the 2 transactions to find out if there are any irregularities (Note 2).

9. For Fact 2, it appears that at the time when the WPL was revoked, the DH was not aware that Dealer 3 had already imported (under an IL of June 2008) 29 carton boxes of medicines (declared to have contained Part I poisons), which should have been recorded in Dealer 3's poisons records and should have been kept in his premises, if not yet re-exported. However, the DH could not detect the omission in Dealer 3's poisons records and, as a result, had not tried to locate the medicines in its visit to his premises in October 2008 (see para. 1 above).

*Source: DH/C&ED records and Audit research*

*Note 1: As informed by the DH in early October 2009, of the 29 carton boxes of medicines seized, 27 related to the medicines under the IL of June 2008 but 2 were not.*

*Note 2: The I&E (Registration) Regulations of the I&E Ordinance have stipulated that any person who knowingly or recklessly lodges any declaration with the C&ED that is inaccurate in any material particular shall be guilty of an offence and shall be liable on summary conviction to a fine of \$10,000.*

5.13 The fact that some dealers might have continued to run poisons business, after their names had been removed from the approved list or their licences had been revoked, is unsatisfactory. Audit considers that the DH needs to explore ways, in collaboration with the Board, to step up the regulatory controls.

5.14 To effectively deter poisons trading without licences by former wholesalers, the DH may wish to explore measures, such as the conduct of surprise inspections, the cancellation of any unused and unexpired ILs and ELs, the use of media releases or publication in the Gazette and on the DH website, to inform the public about the licence revocation. Audit has also suggested in paragraph 3.31 that the DH needs to explore measures to effectively deter improper retail sale of Part II poisons by former LSPs.

#### *Revocation/cancellation of related licences and permits*

5.15 In Case 8, although the DH collected the WPL from Dealer 3 on the day following licence revocation, it had not asked him to surrender other medicine-related licences/permits he still held. Audit noted that, at that time, Dealer 3 was still holding an antibiotics permit issued under the ABO (Note 48) and a wholesaler licence in pCm issued under the CMO.

5.16 Audit further noted that, as at October 2008, Dealer 3 was related to another company (Dealer 5) as they were operated by a common director. The two companies shared largely the same registered office. Dealer 5 was then holding a wholesaler licence in pCm. In December 2008 (2 months after the revocation of Dealer 3's WPL), Dealer 5 applied for a WPL. His application was approved by the WIE Committee in January 2009 (Note 49). Dealer 5 also applied in December 2008 for an antibiotics permit and a wholesale dealer's licence to supply DDs (DDs specified in Part II of the First Schedule to the DDO — Part II DDs), both of which were approved by the DH in January 2009. The deputy person-in-charge of poisons for Dealer 3 was also the person-in-charge for Dealer 5.

5.17 Audit has the following comments:

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**Note 48:** *To deal in antibiotics, a dealer must first obtain an antibiotics permit.*

**Note 49:** *In examining the application for a WPL from Dealer 5, the WIE Committee noted the relationship between Dealer 3 and Dealer 5. In approving the application, the Committee directed that Dealer 5 should be issued with an appropriately worded advisory letter. However, in a letter dated 9 January 2009, Dealer 5 was simply informed to observe the law relating to the scope of a wholesale poisons dealer.*



- (a) once a WPL has been revoked, the dealer can no longer engage in the wholesale of poisons and imports/exports of medicines. **Therefore, at the time of revocation, the DH should have considered revoking the antibiotics permit issued to him (Note 50);**
- (b) Audit is concerned whether it was **in the public interest** for the Board/DH to issue Dealer 5 (who is closely related to Dealer 3) with a WPL, an antibiotics permit and, in particular, a wholesale dealer's licence to supply Part II DDs (Note 51); and
- (c) the DH should have kept the Chinese Medicines Board (Note 52) informed so that the latter can make an informed decision on whether it would be **in the public interest** to renew the pCm wholesaler licences of Dealer 3 and Dealer 5.

5.18 **It appeared that the disciplinary action taken against Dealer 3 might not have been effective in regulating the pharmaceutical trade and in protecting the public interest.** There is a need to step up the regulatory controls over dealers (particularly to review whether tighter criteria should be adopted in approving licences), and to consider related issues when revoking/cancelling any licences.

#### *Audit recommendations*

5.19 **Audit has recommended that the Director of Health should, in collaboration with the Board:**

- (a) **step up the DH regulatory controls over dealers, including the enforcement of disciplinary decisions made by the Board and its committees and taking into account the measures Audit suggested in paragraphs 5.14 and 5.18; and**

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**Note 50:** *According to the DH's guidelines, a dealer holding an antibiotics permit should at the same time be holding either a WPL or an I/E licence. The fact that a dealer is not allowed to carry on any business on wholesale of poisons means that he should no longer hold an antibiotics permit. Section 6 of the ABO also provides that the Director of Health may in his absolute discretion issue an antibiotics permit and may revoke it at any time.*

**Note 51:** *Sections 19 and 20 of the DDO provide respectively that the Director of Health may in his discretion issue a wholesale dealer's licence to supply DDs, and may cancel it at any time.*

**Note 52:** *Sections 136 and 139 of the CMO respectively provide for the power of the Chinese Medicines Board under the Chinese Medicine Council to refuse the renewal of, and to revoke, a wholesaler licence in pCm if the Board considers it necessary in the public interest to do so. The Chinese Medicines Board is chaired by the Director of Health.*

- (b) **follow up on the irregularities identified in paragraph 5.12, including investigation, in consultation with the C&ED, into Case 8 to find out if there are any illegal/improper trading activities.**

## **Response from the Administration**

5.20 The **Director of Health** welcomes the audit recommendations. He has said that the DH will consider follow-up actions in consultation with the DoJ.

## **Effectiveness of licence-refusal criteria and disciplinary actions**

5.21 As mentioned in paragraphs 5.3 and 5.6, the Board and its committees have laid down licence-refusal criteria and disciplinary measures to regulate dealers.

## **Audit observations and recommendations**

### *Need to monitor the effectiveness of newly adopted licence-refusal criteria*

5.22 In the case of licence applications for manufacturers, wholesalers, I/Es and LSPs, Audit welcomes the extension in May 2009 of the licence-refusal criteria to cover **all drug-related convictions** (see para. 5.3(b)). However, the revised licence-refusal criteria have only been adopted for a number of months. Its effectiveness is still subject to test. Audit considers that the DH needs to monitor closely the effectiveness of the newly adopted criteria and report the result at appropriate junctures to the Board and its committees.

### *More relaxed licence-refusal criteria and disciplinary sanctions for ASP*

5.23 As shown in paragraph 5.3, the licence-refusal criteria for ASP are more relaxed in that only convictions relating to psychotropic drugs, zopiclone or cough medicines are taken into account. This means that **not all drug-related convictions are covered**. In comparison, the criteria for LSP, which cover all drug-related convictions, are broader.

5.24 Similarly, the disciplinary sanctions imposed on a convicted ASP are relatively lighter as they generally involve the issue of written warning or suspension of licence for a specified period of time only (see para. 5.6). In comparison, the disciplinary sanctions imposed on a convicted LSP are heavier as the Board may remove his name from the list of LSPs.

5.25 Given that ASPs are authorised to sell both Part I and Part II poisons, Audit is concerned about the adoption of more relaxed licence-refusal criteria for ASPs, and the lighter disciplinary sanctions imposed on convicted ASPs. Taking 2008 as an example, 5 ASPs were refused renewal of licences due to the fact that they had fallen within the licence-refusal criteria. Had all convictions under the PPO, the ABO or the DDO been considered (as similarly adopted for considering licence applications in the case of LSPs — see para. 5.3), it is reckoned that 11 more ASPs would not have been allowed to renew their licences for 2009.

5.26 As at the end of 2008, there were 500 ASPs and 3,300 LSPs. As mentioned in Table 5 in paragraph 5.4, ASPs had 60 conviction cases while LSPs had only 6 cases in 2008. The fact that ASPs had a higher ratio of convictions (60 to 500) than that for LSPs (6 to 3,300) also indicates a need to review the more relaxed ASP licence-refusal criteria and the lighter disciplinary sanctions.

*Related ASPs with multiple convictions still in business*

5.27 There were ASPs with multiple drug-related convictions, and some of them were run by related parties (e.g. the same person may be the director of more than one ASP). There were also ASPs who, after committing serious offences, closed business to escape punishment, but restarted business at the same premises as new ASPs. Case 9 is an example (more details are at Appendix I).

## Case 9

### 11 related ASPs

#### *Case particulars*

1. In this case, 11 ASPs (ASP1 to ASP11) were largely operated by four persons (W, X, Y and Z). Four of them (ASP1, ASP3, ASP4 and ASP5) were involved in seven convictions:

- (a) in 1994 and 1996, W (as the sole proprietor of ASP1) was convicted for medicine-related offences;
- (b) in June 2004, ASP3 (with W and X as directors) was convicted;
- (c) both in June 2005 and April 2006, ASP4 (with X and Y as directors) was convicted, with the conviction in June 2005 for various offences including illegal sale of cough medicines (Part I poisons);
- (d) in March 2007, ASP5 (with Y as director) was convicted. In August 2008, ASP5 was closed. In the same month, ASP10 (with Z as director) started operation on former ASP5's premises; and
- (e) in September 2008, ASP4 (then with W and Z as directors) was again convicted of various offences, including improper storage of a psychotropic substance (a Part I poison).

2. In joint operations carried out by the C&ED and the DH in early 2009, ASP3, ASP4, ASP6, ASP8, ASP9 and ASP10 were again found to have committed offences. As at 30 September 2009, these 6 ASPs were under C&ED investigation.

3. In May 2009, ASP4 (see para. 1(c) and (e) above) was closed. In the same month, the DH received an application for operating another ASP (with Z as one of the two directors) on former ASP4's premises. In September 2009, the Board decided to defer consideration of the application until conclusion of the C&ED investigation/prosecution (see para. 2 above).

4. As at 30 September 2009, seven ASPs were still in business. They were ASP3, ASP6, ASP7, ASP8, ASP9, ASP10 and ASP11.

#### *Audit comments*

5. The ASPs under operation by W, X, Y and Z as proprietors/directors had multiple convictions. Despite this, the companies operated by W, X, Y and Z were still allowed to register as ASPs, to renew their ASP licences annually and to continue business.

5.28 In Case 9, ASP4 had three convictions registered against him from June 2005 to September 2008, as follows:

- In **June 2005**, ASP4 was convicted of selling a Part I poison without the supervision of a registered pharmacist, selling a Part I Third Schedule poison without a prescription, selling poison without proper labelling and failing to store Part I First Schedule poison in a locked receptacle. ASP4 was fined \$50,000 by the court for the offences. In May 2006, the Disciplinary Committee held an inquiry against ASP4 and directed that ASP4 should be **disqualified from being an ASP for a period of one week**. Nonetheless, the Board allowed ASP4 to renew his licence in January 2007.
- In **April 2006**, ASP4 was convicted of selling a Part I Third Schedule poison without the authority of a prescription, selling a Part I poison without the supervision of a registered pharmacist and possession of counterfeit goods for sale. ASP4 was fined \$8,000 by the court for the offences. In July 2008, the Disciplinary Committee held an inquiry against ASP4 and directed that ASP4 should be **disqualified from being an ASP for a period of three weeks**. Despite this, the Board allowed ASP4 to renew his licence in January 2009.
- In **September 2008**, ASP4 was again convicted of selling Part I poison without proper supervision of a registered pharmacist, selling a Part I Third Schedule poison without the authority of a prescription, illegal sale of unregistered medicines, failing to store poison properly and possession of unregistered medicines. ASP4 was fined \$35,000 by the court for the offences. Before the Disciplinary Committee held an inquiry against ASP4, in May 2009, ASP4 was closed.

5.29 **Audit noted that the DH, in recommending new ASP applications for the Board's approval, did not report for the Board's consideration the full information on convictions registered against related ASPs (with the same directors). Take Case 9 as an example:**

- In **October 2006**, in recommending for the Board's approval (Note) of the application for registration of premises of ASP7 (with W as the only director), **the DH did not report the conviction registered in June 2004 against ASP3 (a limited company with W as one of the two directors).**
- In **November 2008**, in recommending for the Board's approval (Note) of the application for registration of premises of ASP9 (operated by a limited company with W as one of the two directors), **the DH did not report the convictions registered in June 2004 and September 2008 against ASP3 and ASP4 respectively (when W was a director of both ASP3 and ASP4).**
- In **February 2009**, in recommending for the Board's approval (Note) of the application for registration of premises of ASP11 (operated by a limited company with W and Z as two of the three directors), **the DH did not report convictions registered in June 2004 and September 2008 against ASP3 and ASP4 respectively (when W was a director of both ASPs and Z was a director of ASP4).**

*Note: In processing all the above three applications, the DH only reported to the Board the convictions against W in 1994 and 1996 when he was the sole proprietor of ASP1. However, because the 1994 and 1996 convictions were registered more than 10 years ago, the DH recommended to the Board that the applications should be approved, subject to satisfactory interview with the persons-in-charge and pharmacists of the applicant companies to ascertain their "fit and proper" status, and subject to satisfactory inspection of the premises. In the event, the Board approved all the three applications.*

5.30 Case 9 demonstrates that there are apparent inadequacies in the DH's checking of ASP registration applications. **Audit considers that the DH needs to step up checking of ASPs' conviction records, particularly checking to determine whether convictions in related ASPs should also be taken into account in assessing whether the applicant is a fit and proper person.** Given the higher ratio of convictions for ASPs (see para. 5.26), the DH needs to critically consider, in collaboration with the Board, whether heavier penalties should be imposed to increase the deterrent effect, including exploring the feasibility of removing ASPs who were not considered fit and proper to continue the retail business of Part I and Part II poisons (as adopted in the case of LSPs).

#### *Audit recommendations*

5.31 **Audit has recommended that the Director of Health should, in collaboration with the Board:**

- (a) **monitor closely the effectiveness of the expanded licence-refusal criteria newly adopted for manufacturers, wholesalers, I/Es and LSPs (see para. 5.22);**
- (b) **critically review whether the licence-refusal criteria for ASP should be expanded to cover all drug-related convictions;**
- (c) **in processing ASP registration applications, step up the DH checking of ASPs' conviction records, particularly checking to determine whether convictions in related ASPs should also be taken into account; and**
- (d) **review the desirability of imposing heavier penalties (such as the removal of ASPs) in appropriate ASP cases to increase the deterrent effect.**

### **Response from the Administration**

5.32 The **Director of Health** welcomes the audit recommendations. He has said that:

- (a) the DH will collaborate with the Board to follow up matters relating to licence-refusal criteria and to review the penalty system for dealers; and
- (b) the DH notes Audit's concern in paragraph 5.29 and will report full information on convictions relating to ASPs and their directors to the Board when considering new licence applications. The DH will seek the DoJ's advice on the proposal in paragraph 5.30 of taking into account convictions in related ASPs when assessing whether the applicant for ASP registration is a fit and proper person.

### **Instigation of disciplinary actions**

5.33 Table 6 in paragraph 5.7 shows that from 2006 to June 2009, the licences of 5 manufacturers/wholesalers had been revoked/suspended, 17 LSPs removed from the LSP list and 48 ASPs suspended from business.

### **Audit observations and recommendation**

#### *Need to take prompt disciplinary actions against ASPs and LSPs*

5.34 To be effective, disciplinary actions against dealers should be promptly taken. For example, in 2008, the Board had taken prompt disciplinary actions against the convicted wholesalers. However, it had not done so for disciplinary actions against the ASPs and LSPs, as shown below:

- (a) **ASPs.** In 2008, the Board had taken disciplinary actions against 23 convicted ASPs after inquiries by the Disciplinary Committee. In 18 cases, the Board had taken **more than 1 year after conviction** to decide on the disciplinary actions (Case 10 is a typical example), with the longest one taking 26 months; and

### Case 10

#### Disciplinary action against a convicted ASP

*Case particulars*

1. On 2 November 2006, an ASP was convicted for selling Part I poison without proper supervision, and was fined \$2,000.
2. The Disciplinary Committee held an inquiry into the case on 6 March 2008 and directed that the ASP should be disqualified for a period of 3 days.

*Audit comments*

3. The disciplinary inquiry was held some **16 months** (November 2006 to March 2008) after the conviction.

*Source: DH records*

- (b) **LSPs.** In 2008, the Board had removed 5 convicted LSPs from the list of LSPs. The Board had taken, on average, 10 months to decide on the disciplinary actions.

5.35 **Audit considers that the DH needs to consider, in collaboration with the Board, ways to expedite disciplinary actions.** Audit found that a long time had been taken for the disciplinary actions against ASPs and LSPs because:

- (a) the Board held meetings quarterly, but the conviction cases were not always brought up to the ensuing Board meeting for discussion; and
- (b) in the case of ASPs, inquiries by the Disciplinary Committee were very often held some 9 to 12 months after the Board discussion.



5.36 The Disciplinary Committee held meetings twice a month and normally only one conviction case was discussed at each meeting. As at 30 September 2009, there were still 21 convicted ASP cases awaiting disciplinary inquiries, with the earliest conviction registered in December 2007. **Given the backlog of cases, Audit considers that the DH needs to consider, in consultation with the Board, ways to expedite the conduct of disciplinary inquiries on the outstanding convicted ASP cases.**

*Audit recommendation*

5.37 **Audit has recommended that the Director of Health should explore, in collaboration with the Board, ways to expedite disciplinary actions, and to clear the backlog of disciplinary cases as early as possible.**

**Response from the Administration**

5.38 The **Director of Health** welcomes the audit recommendation. He has said that the number of disciplinary cases is directly proportional to the number of ASPs convicted by the courts and, as shown in Table 5 in paragraph 5.4, the number of ASPs convicted had doubled from 30 in 2006 to 60 in 2008. To cope with the increased workload, the DH has streamlined its procedures and aims at clearing, by the end of 2009, cases which were convicted prior to June 2009.

## **PART 6: PUBLIC INFORMATION AND INTERNAL SUPPORT**

6.1 This PART examines the adequacy of public information provided by the DH and the adequacy of internal support to help discharge DH regulatory functions.

6.2 Audit findings in this PART are reported as follows:

- (a) public information on medicines and dealers (paras. 6.3 to 6.7); and
- (b) internal support for regulatory work (paras. 6.8 to 6.13).

### **Public information on medicines and dealers**

6.3 To achieve public safety, the DH has to keep the public informed of the potential risks posed by medicines. Answers to questions such as “Has a medicine for sale been registered?”, “Where was it manufactured?”, “Is it a branded or generic product?”, and “Is the dealer selling the medicine licensed?” are very important to the public to enable them to make informed choices on medicines and dealers.

6.4 At present, the DH makes available through its website the following information on medicines and dealers:

- (a) **Medicines:** product name, registration number, holder of registration certificate, address of certificate holder and active ingredients; and
- (b) **Dealers:** names and addresses of all licensed dealers.

### **Audit observations and recommendations**

6.5 Audit has found that there are inadequacies in the public information provided through the DH website, as follows:

- (a) **Information published mainly in English.** Most of the information on medicines and dealers is available in English only. This causes much public inconvenience given that many dealers (such as LSPs) display their names only in Chinese;

- (b) ***Important information relating to registered medicines not available.*** This includes the classification of a medicine under the PPO (e.g. Part I or Part II poison — Note 53), the control on its supply (e.g. whether it is a “prescription-only” medicine) and approved pack sizes together with photo images of the packs;
- (c) ***Information on licensed dealers not timely updated.*** Information on the suspension or removal of dealers’ licences had not always been timely updated to the list of licensed dealers posted on the DH website;
- (d) ***Performance of licensed dealers.*** Audit considers that performance information of licensed dealers is useful to help the public assess the reliability of particular dealers. However, such information (e.g. disciplinary actions) was not displayed on the DH website. Audit noted that the United States Food and Drugs Administration displayed on its website the disciplinary actions taken against non-compliant dealers;
- (e) ***No website for the Board and its committees.*** The Board and its committees play an active role in ensuring public health and safety. For greater transparency, a website should desirably be set up; and
- (f) ***On-line access to register of pharmacists not available.*** At present, the Board publishes the register of pharmacists in the Hong Kong Government Gazette once a year. A register, in paper format, reflecting changes due to addition, removal or suspension of pharmacists during the year is kept at the Board’s office and is available for public inspection during business hours. In the absence of an up-to-date register on the website, the public cannot conduct on-line checking, as and when required, on the registration status of any pharmacists who may be dispensing medicines to them.

### ***Audit recommendations***

#### **6.6 Audit has recommended that the Director of Health should, in collaboration with the Board:**

- (a) **enrich the information on medicines and dealers on the DH website and ensure that the website information is always kept up-to-date; and**
- (b) **consider setting up a website for the Board and upload the register of pharmacists onto the website.**

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**Note 53:** *According to the DH records, as at July 2009, some 9,600 and 1,300 medicines had been registered as Part I and Part II poisons under the PPO.*

## Response from the Administration

6.7 The **Director of Health** welcomes the audit recommendations. He has said that the DH is planning to revamp the website of DH Pharmaceutical Service to provide more information on medicines and dealers.

## Internal support for regulatory work

6.8 The DH manages vast amount of information relating to some 20,000 registered medicines and 5,000 licensed dealers. To effectively discharge its regulatory functions, the DH needs to have proper records and sound information systems to support data analysis, to retrieve useful information, to identify risks, to develop and revise its enforcement strategy, and to deploy its resources.

6.9 The DH maintains both paper records and information systems to support its day-to-day regulatory work. Paper records include case files/records for medicines and dealers, embracing inspection results, laboratory test results, recall reports, investigation results, and prosecution and conviction records. Information systems include the following five computer systems developed since 2003:

- Active Medicines Information and Control System
- Pharmaceuticals Registration and Licensing System
- Pharmaceuticals Import and Export Regulatory System
- e-Pharmaceutical Service System with Licensing On-line Functions
- Adverse Drug Reaction Computer System

The DH spent \$11 million in developing the systems, and needed \$1.7 million a year for maintaining them.

## Audit observations and recommendations

6.10 Although the DH had computerised many of its manual records, Audit noted that there were inadequacies in its record keeping, which might have significantly affected the DH's operational efficiency, as detailed below:

- (a) important operational data were not timely updated to the computer systems, with many computer functions not having been used. For example:

- 
- (i) ***Active Medicines Information and Control System.*** The system was implemented in April 2003. One function was to store information on the results of test purchases, investigations and convictions. However, such operational data had not been input into the system after 2003;
- (ii) ***Pharmaceuticals Registration and Licensing System.*** The system was implemented in April 2003. It maintained a record for each application for medicine registration. However, not all the key data had been input into the system. For example, DH requests for additional information and reasons for delay in approving registration were not recorded in the system. There was a function for uploading the images of medicines onto the system for internal reference by the DH staff, but such function had not been used; and
- (iii) ***Pharmaceuticals Import and Export Regulatory System.*** The system was implemented in November 2005. The system could capture details of the ILs and ELs issued, but it transpired that, owing to resource constraints, most of the licence particulars (e.g. licence number, and names and quantities of medicines to be imported/exported) had not been input into the system. The failure in maintaining a comprehensive IL and EL database has hindered the DH in readily identifying the ILs/ELs issued to a particular licensed trader, and in tracking the movements of unregistered medicines imported for re-export purposes (see para. 2.10(c));
- (b) ***Some useful management information not available.*** The DH regularly submits to the Board statistical information such as the numbers of registered medicines, licensed dealers, inspections and test purchases conducted, prosecutions initiated and convictions registered. Owing to the reasons in (a) above, some important management information could not be produced for the Board's review. Examples are as follows:
- (i) ***Registration of new medicines.*** Important management information includes the number of applications pending approval, ageing analyses of unprocessed applications, and analyses by reasons of delays in processing the applications;
- (ii) ***Inspection results.*** Important management information includes common deficiencies identified in DH inspections and investigations, dealers' compliance with GMP and other licensing requirements, and dealers with repeated offences or persistent adverse inspection results; and
- (iii) ***Recalls and public alerts.*** Important management information includes the numbers of medicine recalls and public alerts issued, recalls by manufacturers/wholesalers and analysis of medicine problems concerned;

- (c) ***Disciplinary history of individual dealers not readily available.*** At present, individual dealers' case files do not contain a complete set of the DH's prosecutions and disciplinary actions taken (e.g. conviction records, non-renewal notices and warning letters). Such prosecutions and disciplinary histories are kept in different files depending on the types of actions taken. Summary control sheets in the individual case files are not always updated. As a result, the disciplinary histories of individual dealers are not readily available; and
- (d) ***Inadequate tools to support inspection work.*** To enhance the quality of DH inspections of dealers' premises and to facilitate the conduct of market surveillance, there is scope for more effective use of IT (such as personal digital assistants or notebook computers) to capture details of registered medicines and licensed dealers.

6.11 In response to Audit's enquiries, in February 2009, DH staff informed Audit that they had not input all the operational data into the computer systems because of resource constraints. They had not fully utilised the computer systems because some of the functions were not user-friendly. Given the various inadequacies in the DH records, Audit considers that the DH needs to conduct an overall review with a view to enhancing its computer systems. To this end, the DH may wish to seek support and assistance from the Efficiency Unit, if appropriate.

#### ***Audit recommendations***

6.12 **Audit has recommended that the Director of Health should:**

- (a) **conduct an overall review of the DH systems with a view to enhancing them to effectively support its regulatory work;**
- (b) **ensure that, once a computer system has been developed, it is properly put into use to reap the expected benefits (such as improving operational efficiency and effectiveness); and**
- (c) **seek support and assistance from the Efficiency Unit, if appropriate, to explore for instance the use of IT to support the DH inspection work.**

#### **Response from the Administration**

6.13 The **Director of Health** welcomes the audit recommendations. He has said that the DH will review the existing supporting system and take steps to upgrade it when the required resources are available.

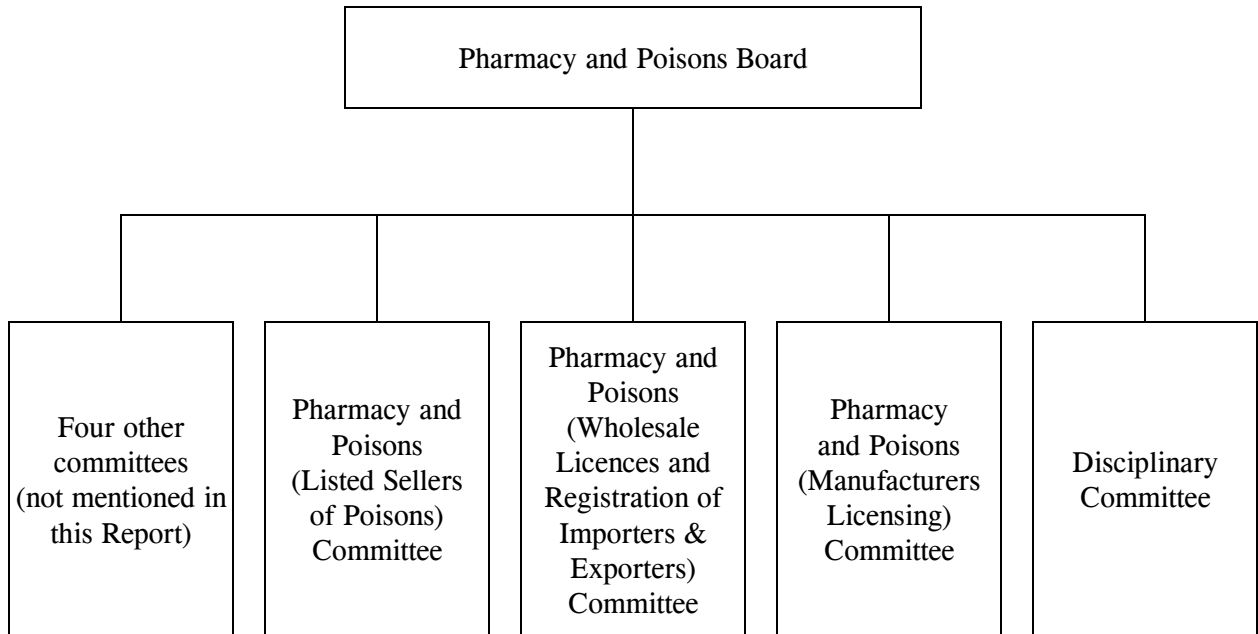
**Key controls over poisons, dangerous drugs and antibiotics at retail level**

<b>Control Legislation</b>	<b>Schedule</b>	<b>Type of scheduled item</b>	<b>Type of retailer</b>	<b>Pharmacist's supervision required</b>	<b>Doctor's prescription required</b>	<b>Record requirement</b>
PPO	<u>Part I, Poisons List</u>					
	1st Schedule	Non-prescription medicines (e.g. cough syrup)	ASP	Yes	No	Poisons book
	3rd Schedule	Prescription-only medicines (e.g. contraceptive pills)	ASP	Yes	Yes	Prescription book
	<u>Part II, Poisons List</u>	Household medicines (e.g. cold remedy)	ASP/ LSP	No	No	N/A
DDO	(Single Schedule)	DDs (e.g. methadone)	ASP	Yes	Yes	DDs register
ABO	(Single Schedule)	Antibiotics (e.g. penicillin)	ASP	Yes	Yes	Antibiotics record book

Legends: *PPO* = *Pharmacy and Poisons Ordinance*  
*DDO* = *Dangerous Drugs Ordinance*  
*ABO* = *Antibiotics Ordinance*  
*ASP* = *authorised seller of poisons*  
*LSP* = *listed seller of poisons*

Source: *Audit research*

**Structure of the Pharmacy and Poisons Board  
(September 2009)**



*Source: Board records*



**Examples of incidents involving unsafe  
and unregistered medicines  
(early 2009)**

1. ***Incident on fungal contaminated Allopurinol.*** On 6 March 2009, one local university announced that four batches of Allopurinol 100mg tablets produced by a local manufacturer were contaminated with *Rhizopus microsporus*. On 9 March 2009, the DH ordered the manufacturer to recall all Allopurinol tablets from the market. The DH investigation revealed that during the production, fungal contamination was caused by a delay of 5 to 14 days in turning the powder into pills. On 30 April 2009, the manufacturer was convicted under the Public Health and Municipal Services Ordinance (Cap. 132) for selling medicines intended for use by man but unfit for that purpose, and was fined \$200,000.
  
2. ***Recall of medicines with incorrect label expiry dates.*** On 11 March 2009, the DH instructed a local manufacturer to recall 216 medicines as their label expiry dates were not substantiated by laboratory data. On 12 March 2009, the Board suspended the manufacturer's licence to facilitate investigations. The case had been reported to the Police. On 3 June 2009, the Board decided to restore the manufacturer's licence. As at end of August 2009, the DH was awaiting the DoJ's advice on whether the manufacturer should be prosecuted.
  
3. ***Supply of unregistered medicine to the Hospital Authority (HA).*** On 16 March 2009, the DH found that one medicine, metformin tablets packed in 50 × 10's blister (a kind of diabetic medicine), supplied to the HA by a local manufacturer had not been registered under the PPO. The DH further found that the manufacturer imported 84 boxes of the medicine from the Mainland in December 2008, and 50 boxes were supplied to 2 hospitals of the HA in March 2009. In June 2009, the manufacturer was fined \$6,000 for possession and sale of unregistered medicine.
  
4. ***Suspected unlicensed packaging and forgery of expiry dates.*** On 19 March 2009, a wholesaler was alleged to have been involved in suspected unlicensed packaging of Amitriptyline tablets (a medicine for depression). On 20 March 2009, the DH again found that the expiry dates of two batches of another medicine "Cosalgescic" (a painkiller) were May 2009 and June 2009 respectively, but the expiry dates printed by the wholesaler on his two batches were June 2010. The DH instructed the wholesaler to recall the medicines from the market. As at end of August 2009, the DH was awaiting the DoJ's advice on whether the wholesaler should be prosecuted.

## Appendix C

(Cont'd)

(paras. 1.12, 3.10(b), 3.22, 3.23, 4.11(a) & (b) and 4.27 refer)

5. ***Recall of unregistered medicines.*** On 7 April 2009, the DH instructed a wholesaler to recall from the market five medicines with unregistered sales packs, two of which also carried unregistered medical indications. The five medicines were Dexaltin Oral Paste 50 × 2g tubes per pack, Dopareel 7.5 mg 500 tablets in blister per pack, Dopareel 10 mg 500 tablets in blister per pack, Glutathion 40 tablets per pack and 100 tablets per pack, and Lacspan powder 12 sachets per pack. As at end of August 2009, the DH was considering to seek the DoJ's advice on whether the wholesaler should be prosecuted.

6. ***Recall of medicines for suspected contamination.*** On 22 April 2009, the DH instructed a local manufacturer to recall all batches of a medicine, called "Diurex", as two batches of it had been contaminated by a fungus. The Board considered that the incident was a serious breach of the Hong Kong GMP Guidelines, and decided on 22 April 2009 to suspend the manufacturer's licence. The licence was restored on 4 June 2009.

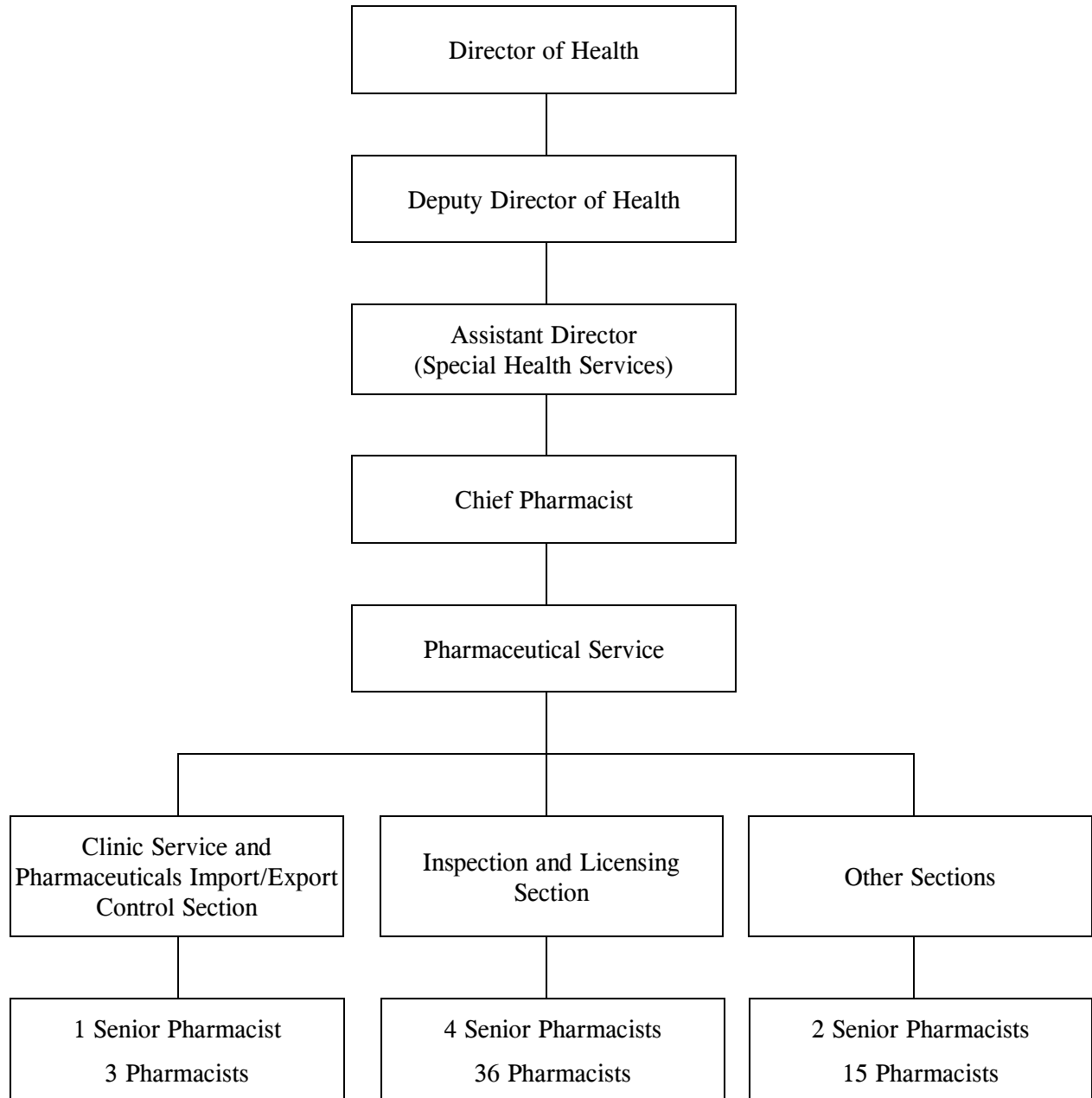
7. ***Public urged not to take a product with undeclared medicine ingredients.*** On 6 May 2009, the DH urged the public not to buy or consume a product called "Neovidan" (療濕痛) which was found to have contained undeclared medicine ingredients that might cause serious side effects. The case had arisen following the DH investigation into a case involving a 65-year-old man who suffered from dizziness and diarrhoea after consuming the product.

8. ***Recall of unregistered oral rehydration salts.*** On 6 May 2009, a wholesaler initiated a recall of an unregistered medicine (Milupa GES 45 Oral Rehydration Salts Sachet) from the market. As at end of August 2009, the DH was considering to seek the DoJ's advice on whether the wholesaler should be prosecuted.

9. ***Recall of medicines in unapproved packages.*** On 7 May 2009, the DH instructed a wholesaler to recall medicines which had been sold in unapproved packages. Based on investigations, the DH found that the wholesaler had sold 46 medicines in unapproved sales packages with unapproved label information. As at end of August 2009, the DH was considering to seek the DoJ's advice on whether the wholesaler should be prosecuted.

Source: LegCo Panel papers, Government News and DH records

Department of Health  
Organisation chart (extract)  
(September 2009)



Source: DH records

**Recommendations announced by Review Committee on 23 October 2009**

The Review Committee announced that it had endorsed the following recommendations:

**Entire medicine supply chain**

*Manufacturers*

- (a) upgrading the current GMP standards of manufacturers to international standards;
- (b) introducing microbiological monitoring for non-sterile medicines during the manufacturing process;
- (c) tightening up the qualification of the Authorised Person (Note) by increasing the required number of years of industrial experience and imposing requirements on training;
- (d) requiring all companies which undertake repackaging activities, including secondary repackaging in addition to primary repackaging, to have a manufacturing licence. A new category of repackaging licence will be introduced for such purpose;

*Wholesalers*

- (e) imposing licensing control on wholesalers of non-poisons in addition to the existing licensing control on wholesalers of poisons;
- (f) tightening the control of wholesalers in terms of licensing conditions, code of practice, record keeping requirements and enhancement of DH inspections;

*Importers and Exporters*

- (g) strengthening the control of the import and export of medicines by deploying a designated team to provide advice to the C&ED at ports of entry and to undertake surveillance work (see para. 2.35 of the Report);

*Retailers*

- (h) imposing licensing control on retailers of non-poisons in addition to the existing licensing control on retailers of poisons;
- (i) requiring, as an ultimate objective, the presence of a registered pharmacist whenever the pharmacy is open for business;
- (j) requiring retailers and doctors to have written records for medicine orders, with a view to ensuring that there is a proper record and checking mechanism to prevent errors during delivery of medicines, which is necessary to protect the safety of patients;

**Medicine procurement and supply in the public and private sectors**

- (k) requiring suppliers to provide the HA and the DH with detailed information on the delivery documentation to enable more effective checking. The HA and the DH would conduct post-delivery surveillance including microbiological and chemical testing;
- (l) encouraging the private medical sector to follow the proposed set of guiding principles to be issued by the DH on medicine procurement;

**Enhancing control of medicines before and after their introduction to the market**

- (m) requiring the conduct of bioavailability and bioequivalence studies for medicine registration;
- (n) requiring the DH to shorten the processing time for approval of medicine registration;
- (o) requiring the DH to continue the extended coverage for the surveillance of high-risk products in the market;

**Pharmacovigilance**

- (p) enhancing pharmacovigilance activity through education, training and promotion among healthcare professionals and the trade, and fostering a culture of awareness of pharmacovigilance;

**Risk communication, education and training**

- (q) requiring the DH to liaise with the pharmacy profession and the tertiary education institutions on training of professionals and members of the trade; and
- (r) provision by the DH of more information on registered medicines to the general public, healthcare professionals and the pharmaceutical industry, and revamping the DH website to include more information and to be more user-friendly.

*Source: Government News*

*Note: An Authorised Person in the manufacturer's premises refers to the person responsible for ensuring the quality of every batch of finished products to be released for sale.*

**Audit attendance at a DH inspection of an ASP  
(March 2009)**

*Case particulars*

1. On 23 March 2009, Audit attended as an observer at a DH routine inspection of an ASP's premises. The 2007 and 2008 DH inspections did not identify any irregularities in the performance of this ASP.
  
2. During the March 2009 inspection, the DH noted the following:
  - (a) a few transactions relating to sales of "prescription-only" medicines were not supported by valid prescriptions (e.g. no doctor's signature);
  - (b) antibiotics and poisons forms were not properly filed in chronological order; and
  - (c) although the registered pharmacist's attendance hours on weekdays had been changed from "10:00 am — 6:00 pm" to "10:00 am — 7:00 pm" in 2007, the sign at the premises still displayed the old attendance hours. The ASP was requested to confirm the attendance hours in writing.
  
3. The DH inspected the ASP's premises again on 3 April 2009, and found that the ASP handled some 2,000 transactions of "prescription-only" medicines a month. An examination by the DH of the prescriptions received by the ASP in February and March 2009 found that 54 prescriptions did not comply with the PPRs (such as no doctor's signature, no dating of the prescriptions, no address of the clinics, amount of the medicine to be supplied not stated and no address of patient). The DH seized the 54 prescriptions and interviewed the managing partner and the registered pharmacist of the ASP. They admitted negligence and that, owing to the large volume of medicine transactions a month, they did not supervise closely the sales of "prescription-only" medicines.

*Audit comments*

4. The DH made a number of observations from its routine inspection in March 2009. In another inspection in April 2009, the DH also found that many sales of "prescription-only" medicines were not supported by valid prescriptions. **Audit considers that the DH needs to review how the quality of its routine inspections of ASPs can be enhanced.** For example, in this case, due to the sharp increase in the number of sales transactions relating to "prescription-only" medicines (rising from "some 200 to 300 transactions a month" in 2005 and 2006 to "some 2,000 to 3,000 transactions a month" in 2007 and 2008), the risk of inadequate supervision for this ASP was high. As a result, the DH should keep in view the propriety of the ASP's sales transactions in future inspections.

*Source: DH records and Audit observations*

**Audit attendance at a DH inspection of an LSP  
(March 2009)**

*Case particulars*

1. On 23 March 2009, Audit attended as an observer at a DH routine inspection of an LSP's premises. The two DH inspections of 2008 did not identify any irregularities in the performance of this LSP.
  
2. During the 2009 inspection, the DH observed the following:
  - (a) the LSP was also selling other products, such as flowers, eggs and Chinese herbal medicines (but was not holding a Retailer Licence in Chinese herbal medicines);
  - (b) the cleanliness of the shop was not satisfactory. The shelves were not clean and tidy;
  - (c) an empty box of medicine was found on the shelf. As explained by the person-in-charge, it was not for sale, but put up there to occupy the space; and
  - (d) there was a pack of another medicine (with expiry date of June 2006) at the far end corner of a shelf.
  
3. Subsequent to the inspection, the PI referred the particulars of the LSP to the Chinese Medicine Division of the DH for follow-up. The DH also conducted another inspection on 30 March 2009. It was found that the shelves had been cleaned and tidied, and the expired medicine had been disposed of.

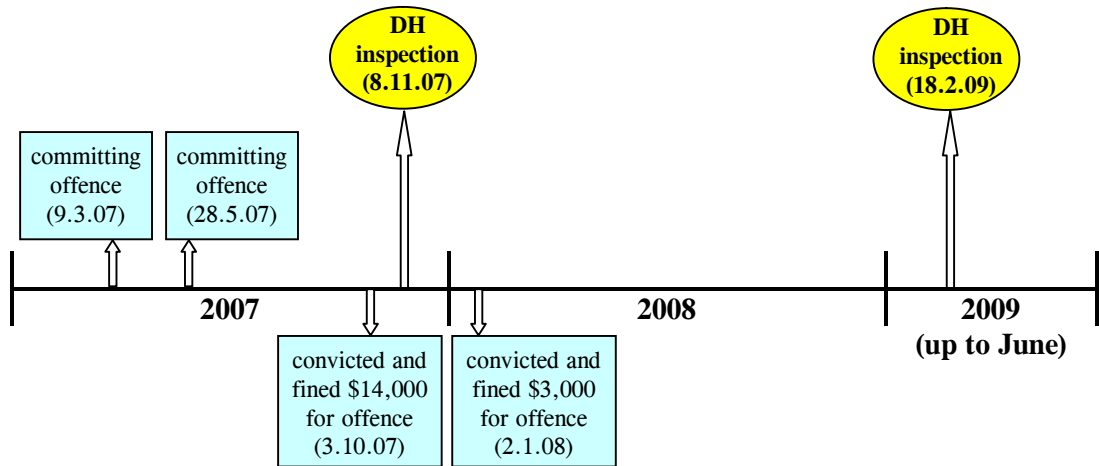
*Audit comments*

4. The DH made a number of observations from this routine inspection.

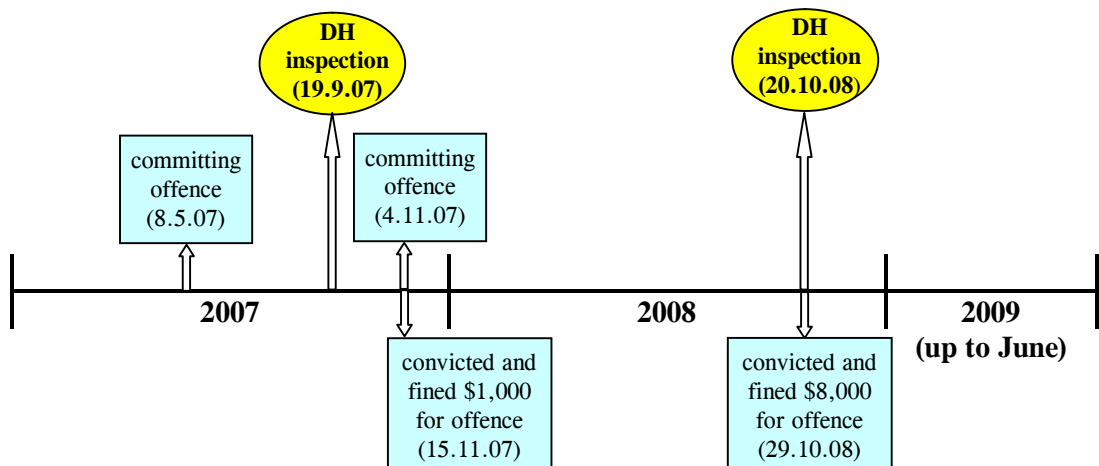
*Source: DH records and Audit observations*

DH inspections of two convicted ASPs

(A) One ASP



(B) Another ASP



Source: Audit analysis of DH records



Case 9

11 related ASPs

*Case particulars*

1. 11 ASPs (ASP1 to ASP11) were largely operated by four persons (W, X, Y and Z), as detailed below.

Location	Particulars
L1	<p>ASP1 (with W as sole proprietor) started operation in June 1993. <b>W was convicted for medicine-related offences in 1994 and 1996.</b> ASP1 was closed in December 2004.</p> <p>ASP6 (with Y as director) started operation at the same location in December 2004. In a joint operation by the C&amp;ED and the DH in early 2009, ASP6 was found to have committed offences. As at 30 September 2009, ASP6 (with X and Z as directors) was under C&amp;ED investigation.</p>
L2	<p>ASP2 (with X as sole proprietor) started operation in October 1998 and was closed in October 2004.</p> <p>In October 2004, ASP5 (with Y as director) started operation at the same location. <b>It was convicted in March 2007.</b> ASP5 was closed in August 2008.</p> <p>In August 2008, ASP10 (with Z as director) started operation. In a joint operation by the C&amp;ED and the DH in early 2009, ASP10 was found to have committed offences. As at 30 September 2009, ASP10 (with X and Z as directors) was under C&amp;ED investigation.</p>
L3	<p>ASP3 (with X as one of the two directors) started operation in March 2002. <b>In June 2004, ASP3 (with W and X as directors) was convicted.</b> In a joint operation by the C&amp;ED and the DH in early 2009, ASP3 was found to have committed offences. As at 30 September 2009, ASP3 (still with W and X as directors) was under C&amp;ED investigation.</p>
L4	<p>ASP4 (with X and Y as directors) started operation in May 2003. <b>In June 2005 and April 2006, ASP4 (still with X and Y as directors) was convicted, with the conviction in June 2005 for various offences including the sale of cough medicines. In September 2008, ASP4 (then with W and Z as directors) was again convicted of various offences including the improper storage of a psychotropic substance.</b> In a joint operation by the C&amp;ED and the DH in early 2009, ASP4 was again found to have committed offences. While ASP4 was closed in May 2009, as at 30 September 2009, it was still under C&amp;ED investigation.</p> <p>In May 2009, the DH received an application for operating another ASP at the same location (with Z as one of the two directors). In July 2009, Audit was successful in test purchases of Part II poisons in the applicant shop (which was unlicensed — see para. 3.30 of the Report). In September 2009, the Board decided to defer consideration of the application until conclusion of the C&amp;ED investigation/prosecution.</p>

**Appendix I**  
(Cont'd)  
(para. 5.27 refers)

<b>Location</b>	<b>Particulars</b>
L5	ASP7 (with W as director) started operation in November 2006.
L6	ASP8 (with Z as director) started operation in May 2007. In a joint operation by the C&ED and the DH in early 2009, ASP8 was found to have committed offences. As at 30 September 2009, ASP8 (with X and Z as directors) was under C&ED investigation.
L7	ASP9 (with W as one of the three directors) started operation in January 2009. In a joint operation by the C&ED and the DH in early 2009, ASP9 was found to have committed offences. As at 30 September 2009, ASP9 was under C&ED investigation.
L8	ASP11 (with W and Z as two of the three directors) started operation in April 2009.

2. As at 30 September 2009, **seven ASPs were still in business** (namely ASP3, ASP6, ASP7, ASP8, ASP9, ASP10 and ASP11).

*Source: DH records and Audit research*

**Acronyms and abbreviations**

ABO	Antibiotics Ordinance
ASPs	Authorised sellers of poisons
Audit	Audit Commission
Board	Pharmacy and Poisons Board
C&ED	Customs and Excise Department
CMO	Chinese Medicine Ordinance
DDO	Dangerous Drugs Ordinance
DDs	Dangerous drugs
DH	Department of Health
DoJ	Department of Justice
EL	Export licence
EMA	European Medicines Agency
FHB	Food and Health Bureau
GL	Government Laboratory
GMP	Good Manufacturing Practice
HA	Hospital Authority
Health Panel	Panel on Health Services

**Appendix J**  
(Cont'd)

I&E Ordinance	Import and Export Ordinance
I/Es	Importers/exporters
IL	Import licence
IT	Information technology
LegCo	Legislative Council
LSP Committee	Pharmacy and Poisons (Listed Sellers of Poisons) Committee
LSPs	Listed sellers of poisons
ML	Manufacturer's licence
ML Committee	Pharmacy and Poisons (Manufacturers Licensing) Committee
pCms	Proprietary Chinese medicines
PIs	Pharmacist inspectors
Police	Hong Kong Police Force
PPO	Pharmacy and Poisons Ordinance
PPRs	Pharmacy and Poisons Regulations
TID	Trade and Industry Department
WIE Committee	Pharmacy and Poisons (Wholesale Licences and Registration of Importers & Exporters) Committee
WPL	Wholesale Poisons Licence