Report No. 53 of the Director of Audit — Chapter 5

CONTROL OF WESTERN MEDICINES

Summary

1. The Department of Health (DH) is responsible for overseeing the safety, efficacy and quality of western medicines (medicines). The Pharmacy and Poisons Ordinance (PPO — Cap. 138) provides for control of the pharmaceutical trade and medicines. A Pharmacy and Poisons Board (Board), with the Director of Health as the Chairman, has been established under the PPO to register medicines and license medicine dealers. As at March 2009, there were some 19,500 registered medicines and 5,000 licensed medicine dealers in Hong Kong. Medicines can be classified as poisons (Part I or Part II), non-poisons, dangerous drugs and antibiotics.

2. A series of incidents in early 2009, involving unsafe and unregistered medicines, have caused great public concern. In March 2009, the Administration announced the setting up of a Review Committee to review the existing regulatory regime for the control of medicines. The Audit Commission (Audit) has recently conducted a review of the control of western medicines. The review was started in January 2009 and has taken into account the medicine incidents and subsequent developments.

Importation of unregistered medicines

3. In recent years, the sale of unregistered medicines in the local market has become a growing public concern. Such unregistered medicines can be illegally/improperly imported into Hong Kong. Under 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. To apply for ILs and ELs, the medicines must have been registered with the Board. However, medicines imported for re-export purposes are not required to be registered.

4. ***Importation of unregistered medicines for re-export.*** The DH issued quite a large number of ILs a month to licensed traders for importing medicines (registered and unregistered) for re-export purposes. Some of these imported medicines were large in quantity or significant in value. Unregistered medicines imported this way might pose a public health risk if they have been distributed for sale or consumption locally. Audit has however found that the DH does not have adequate controls to track the movements of imported medicines for re-export purposes in that: (a) it only refers a small number of ILs/ELs to the Customs and Excise Department (C&ED) for post-shipment consignment checking; (b) it does not require licensed traders to furnish any returns on medicine movements; (c) it did not perform adequate checking on the licensed traders' poisons

records to ensure completeness of recording; and (d) licensed traders are not required under the PPO to keep records of transactions for Part II poisons and non-poisons.

5. ***Impact of inadequacies in control.*** In July 2009, Audit requested the C&ED to verify if the medicines in 15 ILs (issued in 2008) had in fact been re-exported. The results, as at September 2009, showed that: (a) 3 ILs involved improper sales of imported medicines locally instead of re-report; (b) some medicines imported under 6 ILs were still held in stock (for 7 to 16 months), with some stored in unapproved places; and (c) 1 IL involved the re-export of medicines to three countries other than that declared on the licence. The situation is not entirely satisfactory. *Audit has recommended that the Secretary for Food and Health should take the lead to work out a proper strategy to plug the control loophole in the importation of unregistered medicines for re-export purposes.*

6. ***Importation of medicines without licences.*** The I&E Ordinance provides that the import or export of medicine without a licence is an offence. Audit referred 28 suspected transactions to the C&ED for investigation, and it was found that 9 transactions involved the importation of unregistered medicines without ILs. *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.*

Inspection of dealers' activities and other enforcement actions

7. ***Inspection of manufacturers' licensed premises.*** Since 2002, compliance with the Good Manufacturing Practice (GMP) has been a mandatory licensing requirement. The DH inspected manufacturers' premises annually. Audit noted that: (a) before April 2009, GMP inspections were conducted on a pre-arranged basis; and (b) some manufacturers had outsourced their manufacturing to contractors outside Hong Kong, but the DH had not conducted any inspections of these contractors' premises. Many of the medicine incidents in early 2009 related to manufacturers. *Audit has recommended that the Director of Health should: (a) uphold the DH efforts in conducting surprise inspections of manufacturers' premises; (b) consider conducting inspections of the contractors' premises in respect of manufacturing processes outside Hong Kong; and (c) improve the effectiveness and quality of DH inspections.*

8. ***Inspection of wholesalers' and importers/exporters (I/Es)' licensed premises.*** Wholesalers and I/Es are monitored by means of surprise routine inspections. Audit found that, as at 30 June 2009, 39% of 842 wholesalers' premises and 47% of 227 I/Es' premises had not been inspected for over one year. In particular, some wholesalers with convictions or poor performance had not been inspected more frequently. Many of the medicine incidents in early 2009 related to wholesalers. *Audit has recommended that the Director of Health should improve the effectiveness and quality of DH inspections of wholesalers' and I/Es' premises.*

9. ***Inspection of authorised sellers of poisons (ASPs) and listed sellers of poisons (LSPs).*** Only ASPs and LSPs are allowed to sell poisons. Audit was however successful in test purchases of Part II poisons in 17 unlicensed retail shops. Audit also found that ASPs with conviction records were not always inspected more frequently. Although the DH routine inspection results were generally satisfactory and no major non-compliance was found, the DH made various observations in the two routine inspections accompanied by Audit staff. *Audit has recommended that the Director of Health should take steps to strengthen the DH regulatory controls to prevent illegal sales of medicines (including inspecting convicted ASPs more frequently), and review how the quality of the DH routine inspections of ASPs and LSPs can be enhanced.*

10. ***Test purchases.*** The DH conducts test purchases from retailers to detect illegal sale of medicines at the street level. However, the test purchases were normally 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. *Audit has recommended that the Director of Health should review and improve the existing mode of conducting test purchases.*

Medicine testing, recalls and public alerts

11. ***Testing of medicine samples collected from manufacturers' premises.*** In 2008, the DH sent 282 samples collected from manufacturers' premises during inspections to the Government Laboratory (GL) for testing. However, the DH was slow in delivering the samples to the GL and in collecting the test results. There was, on average, a time lag of 168 days and 51 days respectively. In 2009, after the medicine incidents, there have been great improvements overall. For the quarter ended June 2009, the time lag was 26 days and 9 days respectively. *Audit has recommended that the Director of Health should, in collaboration with the Government Chemist, make sustained efforts to further improve the sample testing procedures.*

12. ***Medicine recalls and public alerts.*** In 2008 and 2009 (up to 30 June), there were 42 and 28 medicine recalls respectively. Audit noted that the 2008 recall rates for some medicines were very low and the DH had not taken adequate follow-up actions. Since April 2009, the DH has improved the procedures by requiring its pharmacist inspectors to inspect retail outlets, assess the effectiveness of the recall actions, and determine the need for issuing public alerts. *Audit has recommended that the Director of Health should sustain the DH's enhanced efforts to monitor recall actions taken by manufacturers/wholesalers.*

Licence-refusal criteria, prosecutions and disciplinary actions

13. ***Enforcement of disciplinary actions.*** In the test purchases conducted (see para. 9), Audit found that 4 former LSPs (removed by the Board) were still continuing the retail sale of Part II poisons. In 2008, a dealer's wholesale poisons licence (WPL) was revoked. Audit however noted that, three months after the licence revocation, a related dealer had succeeded in applying for a WPL, an antibiotics permit and a licence to supply dangerous drugs. *Audit has recommended that the Director of Health should, in collaboration with the Board, step up the DH regulatory controls over dealers.*

14. ***Effectiveness of licence-refusal criteria and disciplinary actions.*** 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 three years, all of which involving psychotropic drugs, zopiclone or sale of cough medicines. The licence-refusal criteria for ASP are more relaxed when compared with those for LSP, which cover all drug-related convictions. Besides, the disciplinary sanctions imposed on a convicted ASP are relatively lighter. Audit also found that the Board was not fully informed of the convictions registered against related ASPs when approving new ASP applications. *Audit has recommended that the Director of Health should, in collaboration with the Board: (a) critically review whether the licence-refusal criteria for ASP should be expanded to cover all drug-related convictions; (b) review the desirability of imposing heavier penalties in appropriate ASP cases; and (c) step up the DH checking of conviction records in processing ASP registration applications.*

15. ***Instigation of disciplinary actions.*** Audit found that the Board had not taken prompt disciplinary actions against convicted ASPs and LSPs. For example, in 2008, the Board had taken more than one year after conviction to decide on the disciplinary actions against 18 convicted ASPs. As at 30 September 2009, there were still 21 convicted ASP cases awaiting disciplinary inquiries. *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.*

Public information and internal support

16. ***Public information on medicines and dealers.*** Audit has found that there are inadequacies in the public information provided through the DH website. For example, important information relating to registered medicines (e.g. classification of medicines under the PPO) and performance of licensed dealers (e.g. disciplinary actions) are not provided. There is also no website for the Board. *Audit has recommended that the Director of Health should, in collaboration with the Board, enrich the information on medicines and licensed dealers on the DH website, and consider setting up a website for the Board.*

17. ***Internal support for regulatory work.*** Although the DH had computerised many of its manual records, there were inadequacies in its record keeping, which might have significantly affected the DH's operational efficiency. *Audit has recommended that the Director of Health should conduct an overall review of the DH systems with a view to enhancing them to effectively support its regulatory work.*

Response from the Administration

18. The Administration welcomes this audit review and agrees with the audit recommendations.

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