Control of western medicines

Updated progress of implementing audit recommendations

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Part 1 : Introduction		
1.17	***Review of existing regulatory control of medicines*** Audit recommends 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 regulation and control of medicines in Hong Kong.	The Food and Health Bureau (FHB) attaches great importance to enhancing the regime for the regulation and control of medicines in Hong Kong. In formulating the Government's strategy and preparing legislative amendments to tighten up control, the FHB would take into serious consideration the observations and recommendations of Audit.
Part 2 : Importation of unregistered medicines		
2.20	***Importation of medicines for re-export*** Audit recommends that the Secretary for Food and Health 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;	(a) Regarding the control of the unregistered pharmaceutical products purported for re-export, the Department of Health (DH) has convened a Task Force on Import and Export Control of Pharmaceutical Products with representatives from the FHB, the Commerce and Economic Development Bureau, the Efficiency Unit (EU), the Customs and Excise Department (C&ED), and the Trade and Industry Department (TID) to formulate strategies based on risk assessment.

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	(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.	(b) & (c) With the assistance of the EU, the Task Force is exploring the feasibility of developing a computer system to track the import and re-export of unregistered medicine and the sharing of information among the DH, the C&ED and the TID. Trade consultation is an integral process in the exercise. The Administration would strike a balance between strengthening control and avoiding unnecessary inconvenience to the trade. (d) The Administration will keep the Legislative Council Panel on Health Services informed in due course.
2.31	***Importation of medicines without licences*** Audit recommends 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 importation of medicines.	The Task Force is also exploring ways to step up control over the importation of medicines. The DH has implemented measures such as providing more training to the C&ED front-line staff to enhance their capability in detecting medicines among imported goods; providing the C&ED with an updated list of registered medicines on a regular basis to assist the C&ED in enforcing import and export control at the boundary; and increasing the weekly quota of consignment checking from 18 to 36.
Part 3: Inspection of dealers' activities and other enforcement actions		
3.14	***Inspections of manufacturers' licensed premises*** Audit recommends that the Director of Health should: (a) uphold the DH efforts in conducting surprise inspections of manufacturers' premises;	(a) Since March 2009, the DH has introduced unannounced inspections to manufacturers and will uphold the practice. Between March 2009 and June 2010, the DH has conducted 94 unannounced Good Manufacturing Practices (GMP) inspections against licensed manufacturers.

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	(b) for manufacturing processes that have been outsourced to contractors outside Hong Kong, consider conducting inspections of the contractors' premises; and	(b) As recommended by the Review Committee on Regulation of Pharmaceutical Products in Hong Kong, the DH will enhance the standard of local drug manufacturing in phases and plans to adopt the latest international GMP standards promulgated by the World Health Organisation (WHO) and the Pharmaceutical Inspection Co-operation Scheme (PIC/S). According to the WHO and PIC/S requirements, the DH should conduct inspections of the overseas contractors who take up the outsourced manufacturing process.
	(c) improve the effectiveness and quality of the 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.	(c) On a consultant's advice, the DH will enhance in phases its regulatory functions including the GMP inspections and reporting.
3.25	***Inspections of wholesalers' and importers/exporters' (I/Es) licensed premises*** Audit recommends that the Director of Health should improve the effectiveness and quality of the DH inspections on wholesalers' and I/Es' premises, including the conduct of more frequent and more comprehensive inspections (particularly on those wholesalers with high risk).	The DH conducts inspections on wholesalers and I/Es, and regularly reviews the frequency and the extent of such inspections adopting a risk-based approach. Inspection forms have been revised to strengthen monitoring. Relevant documents are checked before inspection to monitor the import/export status of their medicines.
3.35	***Inspections of authorised sellers of poisons (ASPs) and listed sellers of poisons (LSPs)*** Audit recommends 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;	(a) The DH conducts inspections on ASPs and regularly reviews the frequency and the extent of such inspections according to the conviction records and risk profiles of ASPs.

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	(b) conduct more publicity programmes to enhance the public's knowledge of medicines;	(b) The DH has already enhanced public health education on slimming products and virility drugs through Announcements of Public Interest, pamphlets and thematic websites. The DH will work with other professional bodies and consumer associations to update drug information on the DH's website on a regular basis.
	(c) explore the desirability of imposing a requirement for ASPs/LSPs to display their licences at the entrance of their retail shops;	(c) The DH will, in collaboration with the Pharmacy and Poisons Board (PPB), explore measures such as requiring 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	(d) The DH has already enhanced inspections and test purchases at the removed LSPs and will, in collaboration with the PPB, explore measures such as publishing the removal of LSPs on the DH's website.
	(e) review how the quality of the DH routine inspections of ASPs and LSPs can be enhanced.	(e) The DH conducts inspections on ASPs and LSPs and regularly reviews the frequency and the extent of such inspections adopting a risk-based approach.
3.40	***Market surveillance*** Audit recommends that as a good management practice, the Director of Health should document the DH market surveillance strategy and regularly review and update it to meet changing circumstances.	The current market surveillance strategy and follow up action are based on risk assessment and are reviewed from time to time having regard to market changes, new product information and intelligence. The strategy has been reviewed and documented.
3.46	***Test purchase*** Audit recommends that the Director of Health should review and improve the existing mode of conducting test purchases. In particular, he should consider: (a) conducting test purchases during weekends and night-time; and	(a) The DH has increased test purchases, and started to conduct test purchases during weekends and night-time either on its own or jointly with other law enforcement agencies. Since

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		June 2010, apart from 1,292 test-buy operations conducted during office hour, 94 additional test-buy operations have also been conducted after office hours.
	(b) purchasing different medicine items (based on risk assessment) at different times and different places.	(b) The current strategy of test purchases is based on risk assessment taking into consideration of nature of medicines, which include their potential of abuse and harmfulness, and the location and time of purchase.
Part 4: Medicine testing, recalls and public alerts		
4.15	***Collection of medicine samples for testing*** Audit recommends that the Director of Health should:	
	(a) as regards samples taken from different sources for analysis, review the DH's sample testing requirements each year and, if necessary, liaise with the Government Laboratory (GL) with a view to increasing the agreed test workload;	(a) The DH is working closely with the GL and has initiated an annual review of the number of test samples based on the risk assessment of medicines selected from the market surveillance system. The DH and the GL are exploring the feasibility of increasing the number of samples for testing by 700.
	(b) for testing of samples collected for medicine registration, conduct a post-implementation review to assess whether the streamlined procedures are effective; and	(b) The DH has reviewed the streamlined procedures post-implementation and found them effective.
	(c) for testing of samples collected from manufacturers' premises, in collaboration with the Government Chemist, make sustained efforts to further improve the sample testing procedures; and explore the feasibility of using information technology (IT) to improve the DH's information sharing (such as information relating to the movements of samples and dissemination of the test results) with the GL.	(c) The DH and the GL are working closely with each other and regularly review testing procedures collected from the manufacturers' premises. The DH and the GL have already used IT to streamline the dissemination of test results and conduct regular reviews to identify room for further improvement.

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4.29	***Medicine recalls and public alerts*** Audit recommends 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/ sub-standard 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 the recall actions taken by manufacturers/wholesalers.	(a) & (b) The DH has already reviewed the renewal of registration of medicines. Product licence holders are required to submit a detailed disposal plan to ensure all non-renewed products are removed from the market before the expiry of the product licence. (c) The DH has enhanced the monitoring system on recall. The manufacturers and wholesalers have to submit a distribution list and a detailed recall report of any recalled product. The DH will follow up with post-recall surveillance. The DH will sustain these enhancement efforts.
Part 5: Licence–refusal criteria, prosecutions and disciplinary actions		
5.19	***Enforcement of disciplinary actions*** Audit recommends 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 (b) follow up on the irregularities identified in paragraph 5.12, including investigations, in collaboration with the C&ED, into Case 8 to find out if there are any illegal/improper trading activities.	(a) The DH has obtained legal advice from the Department of Justice (DoJ) that the PPB should take into account circumstances and merits of the particular case in question. The DH will take into account the measures suggested by Audit in the context of the overall review of the regulatory regime and related legislative amendments. (b) The DH and the C&ED followed up on Case 8, Facts 1, 2 and 3 and completed investigation on any illegal/improper trading activities. The DoJ advised no prosecution for Fact 1. For Fact 2, the company concerned was convicted of offences under the Import and Export

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		Ordinance and the Pharmacy and Poisons Ordinance. For Fact 3, there was no evidence of the alleged offence.
5.31	***Effectiveness of licence-refusal criteria and disciplinary actions*** Audit recommends 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; (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.	(a) The DH agrees to closely monitor the effectiveness of the expanded licence-refusal criteria newly adopted for manufacturers, wholesalers, I/Es and LSPs. (b) The PPB has established a working group to critically review the criteria. (c) The PPB has revised the protocol to include the checking of conviction records of the related ASPs when considering applications for ASP registration. (d) The Disciplinary Committee of the PPB has already imposed heavier penalty on ASPs. Legislative amendments are being prepared to enable the removal of ASP licences.
5.37	***Instigation of disciplinary actions*** Audit recommends 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.	The PPB and its Disciplinary Committee have cleared the backlog of disciplinary cases.

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Part 6: Public information and internal support		
6.6	***Public information on medicines and dealers*** Audit recommends 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.	(a) The DH is working closely with different stakeholders to enrich the information on medicines and dealers on the DH website and ensure the information is up-to-date. (b) The PPB will set up a website to promulgate the register of pharmacists.
6.12	***Internal support for regulatory work*** Audit recommends 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 EU, if appropriate, to explore for instance the use of IT to support the DH inspection work.	(a), (b) & (c) The DH is reviewing the existing IT systems of the Pharmaceutical Service and will seek support and assistance from the EU to enhance its regulatory work.