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Panel on Health Services

Updated background brief prepared by the Legislative Council Secretariat for the meeting on 18 November 2013

Regulation of pharmaceutical products in Hong Kong

Purpose

This paper summarizes the concerns of the members of the Panel on Health Services ("the Panel") on issues relating to regulation of pharmaceutical products in Hong Kong.

Background

Regulatory regime for pharmaceutical products

2. The local drug regulatory regime adopts a risk management, dual target and multi-pronged approach underpinned by the Pharmacy and Poisons Ordinance (Cap. 138) ("the Ordinance") and its regulations. The Pharmacy and Poisons Board ("PPB") has been established under the Ordinance to enforce the regulatory measures. PPB is assisted by a Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee, a Pharmacy and Poisons (Manufacturers Licensing) Committee, a Pharmacy and Poisons (Wholesale Licences and Registration of Importers & Exporters) Committee, a Pharmacy and Poisons (Listed Sellers of Poisons) Committee and a Poisons Committee in pursuing its functions relating to the regulation of pharmaceutical products (including Part I Poisons, Part II Poisons and non-poisons[1]) and traders (including manufacturers, importers/exporters, wholesalers and retailers).

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[1] The Ordinance provides for a Poisons List which is divided into two parts: Part I and Part II respectively. Part I Poisons in general are drugs with more serious side effects which warrant enhanced supervision in handling, while Part II Poisons have less serious side effects. Drugs which are not included in the Poisons List are commonly referred to as non-poisons by the traders. Some Part I Poisons are further classified into the First Schedule and the Third Schedule with additional restrictions on their sale at retailers.

3. Under the Ordinance, any person wishing to sell, offer for sale, distribute or possess any pharmaceutical products or substance shall register the product or substance with PPB. Only those pharmaceutical products or substances that conform to the standards on safety, efficacy will be registered. Once the registration is approved, the certificate of registration will be issued for a validity of five years subject to renewal. New registration applications of pharmaceutical products are mainly classified into New Chemical Entity ("NCE") and non-NCE (or commonly known as generic). At present, there are around 19 000 registered pharmaceutical products in Hong Kong.

4. The Ordinance also stipulates that all pharmaceutical traders, except companies trading in pharmaceutical products of non-poisons within Hong Kong, are required to obtain the required licences from PPB. As of September 2013, there are 37 holders of a manufacturer's licence. Among these licensed pharmaceutical manufacturers, 24 of them were in compliance with the Hong Kong Good Manufacturing Practices[2] Guidelines for Pharmaceutical Products. As of October 2013, there were 717 licensed wholesalers of poisons, 94 registered importers and exports of pharmaceutical products, and 4 405 licensed medicine retailers (including 579 authorized sellers of poisons ("ASP") (or commonly known as "dispensaries" or "pharmacies") and 3 826 listed sellers of poisons ("LSPs") (or commonly known as "medicine companies")).

Reviews on the regulation of pharmaceutical products

5. In early 2009, a series of incidents involving unsafe and unregistered pharmaceutical products had caused wide public concern. In the light of the incidents, the Government set up a Review Committee on the Regulation of Pharmaceutical Products in Hong Kong ("the Review Committee") in March 2009 to conduct a comprehensive review on the existing regime for the regulation of pharmaceutical products. In its report issued in December 2009, the Review Committee has made a total of 75 recommendations covering the aspects of (a) regulation of drug manufacturers and Good Manufacturing Practice ("GMP"); (b) pre-market control of drugs; (c) regulation of importers/exporters, wholesalers and retailers; (d) procurement and supply of pharmaceutical products in the public and private medical sectors; (e) post-market control of drugs and Pharmacovigilance; (f) risk communication, education and training; and (g) manpower requirements. The Administration accepted the recommendations of the Review Committee. Among the 75 recommendations, 16 recommendations require amendments to the Ordinance and its subsidiary legislation. Annex E to the report of the Review Committee which sets out these recommendations is in **Appendix I**.

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[2] Good Manufacturing Practice is a quality assurance approach used by the drug manufacturing industry worldwide to ensure that products are consistently produced and controlled according to quality standards appropriate to the products' intended use. According to the Administration, most countries have adopted the set of Good Manufacturing Practice guidelines promulgated by the World Health Organization ("WHO").

6. Separately, the Audit Commission conducted a review on the control of western medicines in 2009. It found inadequacies in the Department of Health ("DH")'s work in (a) importation of unregistered medicines; (b) inspection of dealers' activities and other enforcement actions; (c) medicine testing, recalls and public alerts; (d) licence-refusal criteria, prosecutions and disciplinary actions; and (e) public information and internal support. Its findings were published in the Director of Auditor's Report No. 53. The Report was considered by the Public Accounts Committee ("PAC"), which published its own report (Report No. 53A) with recommendations in June 2010. PAC has urged the Administration to accord top priority to the ensuring of the safety, efficacy and quality of medicines in Hong Kong, and expeditiously implement the recommendations of the Review Committee, including seeking the necessary manpower resources and introducing required legislative proposals to improve the regulation and control of medicines. The conclusions and recommendations of PAC which are extracted from its report are in **Appendix II**.

Deliberations of the Panel

7. After the occurrence of the incidents concerning pharmaceutical products in 2009, the Panel discussed issues relating to the regulation and control of pharmaceutical products in Hong Kong at three meetings between 2009 and 2011. The deliberations and concerns of members are summarized below.

Regulation of manufacturers

8. Noting that the spirit of GMP emphasized that the assessment of good quality should be based on scrutiny of the manufacturing process and not by testing of the end products alone, members considered it important to ensure proper quality control at the upstream of the supply chain, i.e. the manufacturers. Given that many of the incidents in early 2009 related to manufacturers, they expressed grave concern about the effectiveness of the measures putting in place by DH in monitoring the manufacturing process. There were views that DH should conduct more detailed inspections to the licensed pharmaceutical premises, such as conducting unannounced inspections and revising the inspection checklists to enhance the quality of inspections.

9. The Administration advised that all pharmaceutical manufacturers had to meet the licensing requirements before they could obtain a licence from PPB. To ensure that pharmaceutical products were consistently produced and controlled throughout the manufacturing process, compliance with GMP had since 2002 become an additional important licensing condition. DH would conduct inspections against the licensees once or twice a year to ensure their compliance with GMP and other regulatory requirements. During inspections,

all different GMP aspects would be audited for compliance against a checklist and product samples would be taken for analysis. As a next step, DH would conduct surprise inspections of the licensees and revise the inspection checklist.

10. Members were concerned that while WHO had upgraded its GMP in 2007, Hong Kong was still adopting the GMP standard promulgated by WHO in 1995, and the compliance of which was not a mandatory legal requirement. According to the Administration, it would follow the recommendation of the Review Committee to upgrade Hong Kong's current GMP licensing standard to the standard promulgated by WHO in 2007 in about two years' time, and in about another two years' time to upgrade it to the even higher Pharmaceutical Inspection Cooperation Scheme standard so as to be on par with international best practice.

11. On the view that local pharmaceutical manufacturers should be required to engage external auditors to ensure they conformed to the GMP standards, the Administration advised that it would consider the suggestion.

Regulation of importers/exporters and wholesalers

12. In the absence of a record and tracking system to trace if pharmaceutical products imported into Hong Kong for re-export purpose were indeed exported, some members urged the Administration to expeditiously formulate measures to prevent the illegal sale of imported unregistered pharmaceutical products in local market.

13. The Administration advised that DH would set up a record and tracking system so that export licence applicants would be required to produce the relevant import licences of the imported drugs to be re-exported. In the long run, an electronic record system which was inter-operable with the Customs and Excise Department ("C&ED") and the Trade and Industry Department should be a more efficient alternative. In addition, C&ED would, after having taken into account the workload of its staff, increase the weekly quota of post-shipment consignment checks of licence. The Administration also planned to require wholesalers and retailers handling non-poisons to apply for a licence and to require wholesalers to keep transaction records of all pharmaceutical products.

Regulation of retailers

14. Concern was raised about the failure of the existing regulatory regime to prevent those ASPs who closed business to escape punishment after committing serious offences from restarting business at the same premises as new ASPs. There were also cases that ASPs and LSPs with drug-related convictions could successfully restart and operate new ASPs and LSPs because the directors of the convicted ASPs and LSPs might not be personally convicted of the offence.

Members also expressed concern that PPB could only revoke the ASP licence for a period of time or not renew the licence upon expiry in extreme situation. They called on the Administration to improve the existing regulatory regime for drugs retailers.

15. The Administration advised that to step up the regulation of drug retailers, DH would conduct more frequent unannounced inspections, in particular to those with a poor record of law compliance. It also planned to amend the Ordinance to give PPB the authority to revoke the licence of an ASP at any time when the ASP concerned had committed a serious drug offence.

16. Members noted that the Ordinance, which currently required a registered pharmacist to be present in an ASP for not less than two-third of its opening hours, would be amended to the effect that the registered pharmacist concerned should be present whenever the ASP was opened for business. There was concern that this would increase the operating cost of ASPs, which in turn might be passed on to consumers. The requirement might also result in ASPs being monopolized by large consortia. In the Administration's view, this would not be the case as the requirement would be applicable to all ASPs. The requirement would also increase consumer confidence over ASPs. DH would work out the timetable for implementing the requirement after having taken into account the market conditions and manpower supply of registered pharmacists.

Penalty system

17. Members were advised that the Ordinance would be amended to include provisions for the court to order the convicted person to pay the analytical costs incurred by the Government and to give PPB the authority to revoke the licence of a convicted ASP at any time to increase deterrent effect. There were views that this apart, the existing maximum fines for non-compliance of the Ordinance, i.e. a fine of $100,000, should be increased to the range of $500,000 to $1 million to deter the pharmaceutical traders from malpractices. There was also a view that a demerit point system for licensed medicine retailers should be introduced.

Establishment of a dedicated office on drugs

18. Members in general were of the view that inadequate manpower support had affected the effectiveness of DH in discharging its responsibility to carry out inspections and surveillances of the pharmaceutical supply chain. While supporting the proposal put forward by the Review Committee to expand and reorganize the Pharmaceutical Service of DH into a dedicated office on drugs ("the Drug Office"), members were concerned about whether the additional manpower requirement required for implementing the 75 recommendations of the Review Committee could be met through local supply.

19. According to the Administration, the Pharmaceutical Service of DH would need to increase staff strength from around 160 to more than 350 in order to implement all the recommendations of the Review Committee in full. The Administration would, having taken into account the supply of overseas pharmacy graduates, liaise with the University Grants Committee with a view to increasing the number of student places of tertiary institutions for the pharmacy discipline.

Recent developments

20. The proposal of creating two permanent posts of one Assistant Director of Health (D2) and one Chief Pharmacist (D1) in DH to provide dedicated directorate support for the establishment of the Drug Office was approved by the Finance Committee in June 2011. The Pharmaceutical Service of DH was re-organized into Drug Office in September 2011 to strengthen various existing regulatory activities on pharmacovigilance, import/export, manufacture, wholesale and retail licensing; inspections; surveillance and complaint investigation. In addition, new areas of work including risk assessment and risk communication were introduced to enhance control on pharmaceutical products for better public health protection.

21. According to the Administration, it has commissioned a consultancy service for the upgrade of GMP licensing standards in August 2012. The study is expected to complete in August 2014.

Relevant papers

22. A list of the relevant papers on the Legislative Council website is in **Appendix III**.

Council Business Division 2
Legislative Council Secretariat
15 November 2013

Annex E to the Report of the Review Committee on Regulation of Pharmaceutical Products in Hong Kong

Recommendations Requiring Legislative Amendments

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

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

Regulation of Wholesalers

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

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

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

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

Regulation of Importers and Exporters

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

Regulation of Retailers

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

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

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

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

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

Pre-market control of drugs

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

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

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

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

Penalty

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

75. Regarding the progress made by the DH in addressing the adequacies in its computer systems as set out in paragraph 6.10 of the Audit Report, the **Director of Health** informed the Committee in his letter of 11 March 2010 that:

- the DH planned to develop a new computer database for registration of medicines in September 2009 in consultation with the Office of the Government Chief Information Officer. The new system was designed to streamline the input of key data of registered medicines such as pack size, quantity of active ingredient, product image, etc; and

- as recommended by the Review Committee, the DH would set up a record and tracking system for import and export of medicines. The DH was also in liaison with the Efficiency Unit to seek its support and assistance to conduct a feasibility study in developing an integrated IT system among the DH, the C&ED and the Trade and Industry Department to enhance control and to optimise the utilisation of other IT systems within the Pharmaceutical Service of the DH.

G. Conclusions and recommendations

76. The Committee:

- considers it is of paramount importance that the Department of Health ("DH") discharges effectively its duty to ensure the safety, efficacy and quality of medicines marketed in Hong Kong because if medicines are not properly regulated, Hong Kong people would be exposed to potential health and safety risks;

- expresses grave dismay and finds it unacceptable that the Secretary for Food and Health and the Director of Health have failed to attach sufficient importance to the regulation and control of medicines in Hong Kong, as reflected by the following and detailed in the ensuing parts:

  (a) the existing regulatory regime allows some unregistered medicines to be distributed for sale or consumption in Hong Kong;

  (b) the inspections of dealers' activities and enforcement actions by the DH are ineffective;

  (c) there are inadequacies in the DH's procedures on medicine testing, monitoring of medicine recalls and issuing of public alerts, as well as in the DH's prosecutions and disciplinary actions on dealers; and

(d) it was only after the occurrence of a series of incidents involving unsafe and unregistered medicines in early 2009 ("the incidents") that the Food and Health Bureau ("FHB") and the DH took actions to step up the control of medicines and establish the Review Committee on Regulation of Pharmaceutical Products in Hong Kong ("Review Committee") to undertake a comprehensive review of the existing regime for the regulation and control of medicines;

Review of existing regulatory control of medicines

- expresses grave concern over the inadequacies in the regulatory regime as revealed by the incidents in early 2009 and by this audit review;

- acknowledges that:

  (a) the Review Committee published its report ("Review Report") in January 2010 which contained a range of recommendations on the measures to improve the existing regulatory regime. One of the recommendations is to set up a new dedicated office on drugs to strengthen the regulatory role of the Government in enhancing drug safety;

  (b) the FHB will take into account the audit observations and recommendations in implementing the recommendations of the Review Committee; and

  (c) the Government will take follow-up actions to implement the measures recommended in the Review Report. The FHB will take charge of the policy issues and, together with the DH, study the legislative amendments required and address the resource implications involved. The trade and other stakeholders will be consulted before the legislative proposals are submitted to the Legislative Council ("LegCo");

- strongly urges the Secretary for Food and Health and the Director of Health to accord top priority to ensuring the safety, efficacy and quality of medicines in Hong Kong and expeditiously implement the recommendations of the Review Report, including seeking the necessary manpower resources and introducing the required legislative proposals to improve the regime for the regulation and control of medicines;

Importation of unregistered medicines

- notes that under the Pharmacy and Poisons Regulations of the Pharmacy and Poisons Ordinance (Cap. 138) ("PPO"), medicines imported for re-export purposes are not required to be registered with the DH;

- considers it inexcusable and condemns the Director of Health for the following:

  (a) the sale in Hong Kong of unregistered medicines purportedly imported for re-export purposes has been allowed to continue despite the growing public concern;

  (b) although the DH issues hundreds of import licences ("ILs") a month for the importation of medicines for re-export purposes, it only refers 18 licences (including both ILs and export licences ("ELs")) to the Customs and Excise Department ("C&ED") each week for post-shipment consignment checking. This weekly quota has remained unchanged for many years despite the increasing number of ILs and ELs in recent years;

  (c) the DH has failed to put in place adequate controls to track the movement of imported medicines for re-export purposes, as detailed in paragraph 2.10 of the Director of Audit's Report ("Audit Report"). In the absence of adequate controls, some unregistered medicines might have been distributed for sale or consumption in Hong Kong;

  (d) an examination in July to September 2009 by the Audit Commission ("Audit") of 15 ILs revealed various irregularities, including improper sales of medicines locally which were imported for re-export purposes, and some medicines being stored in unapproved places;

  (e) there was inadequate assurance that all the unregistered medicines (involving Part I poisons and antibiotics) imported by a wholesaler referred to in paragraph 2.12(e) of the Audit Report had in fact been re-exported. There was a risk that some of the unregistered medicines might have been distributed for sale or consumption in the local market;

  (f) although the DH was aware of the risks associated with importation of unregistered medicines for re-export purposes as early as 1999, it failed to step up control in this regard;

  (g) although the LegCo Panel on Health Services ("Health Panel") was informed in March 2000 that the Pharmacy and Poisons Board ("Board") would implement a revised arrangement of regulating the importation of unregistered medicines for re-export purposes, neither the Board nor the DH had informed the Health Panel of subsequent developments, including the shelving of the arrangement proposed and the need for legislative amendments to implement an alternative control measure. For the nine years from 2001 to 2009, no progress had been made in the submission of legislative proposals to the LegCo;

(h) in the 10 years since the DH decided not to follow up the proposal of devising a computer system to monitor the import and export of medicines made by a pharmaceutical trade association in 1999 due to the opposition by small to medium size pharmaceutical importers/exporters for reason that it would cause operational difficulties, the DH has failed to explore further the feasibility of computerisation in the light of advances in information technology ("IT"); and

(i) of the 28 transactions referred by Audit (paragraph 2.28(e) of the Audit Report) to the C&ED for investigation, nine transactions were found to have involved the importation of unregistered medicines without IL in contravention of the requirements under the Import and Export Ordinance (Cap. 60);

- acknowledges that:

(a) to prevent illegal diversion of pharmaceutical products imported for re-export purposes into the local market, the Review Committee has recommended strengthening the control and tracking of the import and export of such products, including:

(i) the DH should set up a record and tracking system to require EL applicants to produce the relevant ILs, so that the DH staff can keep track of the amount imported and exported; and

(ii) the DH should prescribe in the licensing conditions for ILs for the products for re-export that the importer should not sell unregistered imported pharmaceutical products in Hong Kong and must re-export the products within a specified period of time;

(b) the Director of Health has agreed with Audit's view in paragraph 2.10(c)(iii) of the Audit Report that, as part of the DH inspection of wholesalers' premises, there should be checking of transactions from the DH departmental licence copies to the wholesalers' poisons records to ensure completeness of recording;

(c) the Director of Health shares Audit's concerns that more licences should be selected for post-shipment consignment checking by the C&ED based on risk assessment, and the Review Committee has recommended that the DH conducts joint review with the C&ED to determine a new weekly quota which represents a statistically significant sample size of the ILs and ELs population;

(d) the Director of Health welcomed the audit recommendation in paragraph 2.31 of the Audit Report;

(e) the Commissioner of Customs and Excise has accepted the audit recommendation in paragraph 2.31 of the Audit Report; and

(f) the Director-General of Trade and Industry has said that the Trade and Industry Department would be pleased to render support to the DH as far as possible to implement the audit recommendations in paragraphs 2.20 and 2.31 of the Audit Report;

- strongly urges the Director of Health to:

(a) work closely with other relevant bureaux and departments to implement without delay the above recommendations of Audit and the Review Committee to tighten up the import and export control of pharmaceutical products; and

(b) keep the LegCo (including the Health Panel) informed of subsequent developments of the matters on which the LegCo has been consulted previously and seek the views of the LegCo on the new developments as appropriate;

Inspection of dealers' activities and other enforcement actions

- notes that in April 2009, the DH started to conduct surprise inspections of Good Manufacturing Practice certified manufacturers;

- considers the following deficiencies of the DH's inspections and enforcement actions inexplicable and unacceptable:

(a) some manufacturers had outsourced their manufacturing to contractors outside Hong Kong, but the DH had not conducted any inspections of these contractors' premises;

(b) work done on the DH's inspections of manufacturers' premises was not adequately documented;

(c) many of the incidents in early 2009 related to manufacturers and wholesalers, but efforts to improve the effectiveness, frequency and quality of its inspections were not stepped up;

(d) some manufacturers and wholesalers with poor performance or conviction records had not been inspected more frequently;

(e) as at 30 June 2009, 39% of 842 wholesalers' premises and 47% of 227 importers/exporters' premises had not been inspected for over one year;

(f) whilst only authorised sellers of poisons ("ASPs") and listed sellers of poisons ("LSPs") are allowed to sell poisons, Audit was successful in test purchases of Part II poisons in 17 unlicensed retail shops;

(g) although the DH's past inspection results of two retailers were satisfactory and no major non-compliance was found, in the two routine inspections accompanied by Audit staff, the DH made various observations, thus casting doubt on the quality of the previous inspections;

(h) the DH had not always inspected convicted ASPs more frequently and the average rate of inspecting twice a year for such ASPs was not always achieved;

(i) whilst the DH had a market surveillance strategy in place, it had not documented the strategy;

(j) routine test purchases were not carried out during weekends and night-time when illegal sale of Part I poisons might be more prevalent; and

(k) the four DH staff responsible for conducting test purchases were assigned to purchase the same medicines for a number of months;

- acknowledges that:

(a) the Director of Health has agreed with the audit recommendations in paragraphs 3.14, 3.25, 3.35, 3.40 and 3.46 of the Audit Report; and

(b) the Review Committee has recommended that the DH strengthens the monitoring of ASPs and LSPs by means of more frequent and more detailed inspections;

- strongly urges the Director of Health to implement expeditiously the above recommendations of Audit and the Review Committee, and explore proactively other measures to improve the frequency, quality and effectiveness of its inspections and enforcement actions;

<u>Medicine testing, recalls and public alerts</u>

- expresses grave dissatisfaction about the inadequacies and loopholes in the DH's procedures on medicine testing, monitoring of medicine recalls and issuing of public alerts, indicating that the DH did not accord a high priority to this area of work which is an integral part of the regulatory regime to ensure the safety of medicines:

(a) since 2 January 2009, the DH has removed the requirement that applicants have to submit medicine samples for testing by the Government Laboratory ("GL") before approving their medicine registration. There may be risks associated with the adoption of this new procedure;

(b) in 2008, the DH had not promptly delivered the 282 samples collected from manufacturers' premises to the GL for testing, and had been slow in collecting the GL test results for follow-up;

(c) there were no DH guidelines to assist pharmacist inspectors in making decisions on when they should request manufacturers/wholesalers to take recall actions;

(d) the DH had no procedures for requiring manufacturers/wholesalers to recall medicines with expired registration. There were medicines, the registration of which had expired, still available for sale in the market;

(e) the medicine recall reports submitted by many manufacturers and wholesalers in 2008 did not provide adequate information for evaluating the effectiveness of the recall actions. Besides, the medicine recall rates were generally very low and the DH had not taken adequate follow-up action; and

(f) in relation to defective medicines identified in 2008, there were instances where the DH had not issued any public alerts or the public alerts were not issued promptly;

- acknowledges that:

(a) in 2009, after the medicine incidents, the DH has expedited action in delivering medicine samples (collected from manufacturers' premises) to the GL for testing and in collecting the GL test results, and the GL has also speeded up its testing work;

(b) the DH, in consultation with the GL, is exploring the setting of performance targets for the turnaround time of testing of samples and the outsourcing of certain testing work;

(c) since April 2009, the DH has improved its procedures on recalls and public alerts by requiring its staff to inspect the retail outlets, and assess the effectiveness of the recall actions taken by manufacturers/wholesalers and the need for issuing public alerts;

(d) the DH is studying the Review Committee's recommendation on the inclusion of a refund mechanism in the DH's recall guidelines to require manufacturers and wholesalers to provide refund details to consumers at retail level in the event of medicine recalls;

(e) the Director of Health has agreed with the audit recommendations in paragraphs 4.15 and 4.29 of the Audit Report; and

(f) the Government Chemist has agreed with the audit recommendations in paragraph 4.15 of the Audit Report;

- strongly urges the Director of Health to:

(a) accord a high priority to medicine testing, monitoring of medicine recalls and issuing of public alerts to ensure that this area of work is properly carried out;

(b) finalise as soon as practicable with the GL the performance targets for the turnaround time of testing of samples and the outsourcing of certain testing work; and

(c) implement expeditiously the above audit recommendations and the relevant recommendations of the Review Committee;

Licence-refusal criteria, prosecutions and disciplinary actions

- expresses astonishment and finds it unacceptable that the following enforcement problems could be tolerated:

(a) some former LSPs were still continuing the retail sale of Part II poisons after their removal from the LSP list due to convictions;

(b) there were indications that a dealer, whose wholesale poisons licence ("WPL") had been revoked in October 2008, might still be involved in poisons business after licence revocation, and in January 2009 a related dealer had succeeded in applying for a WPL, an antibiotics permit and a licence to supply dangerous drugs;

(c) in comparison with LSPs, the licence-refusal criteria for ASPs were more relaxed as they did not cover all drug-related convictions. Similarly, the disciplinary sanctions imposed on a convicted ASP were relatively lighter, involving the issue of warning or suspension of licence for a specified period of time only;

(d) there were some related ASPs with multiple drug-related convictions. Some of them closed business after committing serious offences, but restarted business at the same premises as new ASPs. However, the Board was not fully informed of the convictions registered against related ASPs when approving new ASP applications; and

(e) the Board had not taken prompt disciplinary actions against 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;

- acknowledges that:

(a) the Director of Health has agreed with the audit recommendations in paragraphs 5.19, 5.31 and 5.37 of the Audit Report; and

(b) the Review Committee has made a number of recommendations to step up the regulation of importers/exporters, wholesalers and retailers, including strengthening the licensing system and introducing new licensing conditions, as well as enhancing the existing penalty system under the PPO for better deterrence;

- strongly urges the Director of Health to implement without delay the above recommendations of Audit and the relevant recommendations of the Review Committee to improve the DH's prosecutions and disciplinary actions as well as the penalty system, thereby achieving greater deterrent effect and protecting the public interest;

<u>Public information and internal support</u>

- expresses concern that:

(a) there are inadequacies in the public information provided through the DH's website; and

(b) although the DH had computerised many of its manual records, there were inadequacies in its record keeping, which might have significantly affected its operational efficiency;

- acknowledges that:

(a) the Director of Health has agreed with the audit recommendations in paragraphs 6.6 and 6.12 of the Audit Report;

(b) the DH has planned to develop a new computer database for registration of medicines in consultation with the Office of the Government Chief Information Officer, with a view to streamlining the input of key data of registered medicines; and

(c) the DH is in liaison with the Efficiency Unit to seek its support and assistance to conduct a feasibility study in developing an integrated IT system among the DH, the C&ED and the Trade and Industry Department to enhance control and optimise the utilisation of other IT systems within the DH's Pharmaceutical Service; and

Follow-up actions

- wishes to be kept informed of:

(a) the outcome of the DH's discussion with the GL on the setting of performance targets for the turnaround time of testing of samples and the outsourcing of certain testing work; and

(b) the progress made in implementing the various audit recommendations and the developments in following up the recommendations of the Review Committee.

Appendix III

Relevant papers on the regulation of pharmaceutical products in Hong Kong

Committee	Date of meeting	Paper
Panel on Health Services	31.3.2009 (Item I)	Agenda Minutes CB(2)2139/08-09(01)
Panel on Health Services	11.1.2010 (Item V)	Agenda Minutes
Panel on Health Services	11.4.2011 (Item VI)	Agenda Minutes

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