SUPPLEMENTAL REPORT OF THE

PUBLIC ACCOUNTS COMMITTEE

ON

REPORT NO. 53 OF THE DIRECTOR OF AUDIT

ON

THE RESULTS OF

VALUE FOR MONEY AUDITS

June 2010

P.A.C. Report No. 53A

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The Establishment of the Committee The Public Accounts Committee is established under Rule 72 of the Rules of Procedure of the Legislative Council of the Hong Kong Special Administrative Region, a copy of which is attached in ***Appendix 1*** to this Report.

2. **Membership of the Committee** The following Members are appointed by the President under Rule 72(3) of the Rules of Procedure to serve on the Committee:

Chairman	**:**	Dr Hon Philip WONG Yu-hong, GBS
Deputy Chairman	**:**	Hon Paul CHAN Mo-po, MH, JP
Members	**:**	Hon Andrew CHENG Kar-foo Hon Abraham SHEK Lai-him, SBS, JP Hon Alan LEONG Kah-kit, SC *(until 28 January 2010)* Hon Ronny TONG Ka-wah, SC *(with effect from 26 February 2010)* Hon Cyd HO Sau-lan *(with effect from 26 February 2010)* Hon Starry LEE Wai-king Hon WONG Yuk-man *(until 28 January 2010)*
Clerk	**:**	Ms Miranda HON Lut-fo
Legal Adviser	**:**	Mr Arthur CHEUNG

3. According to Rule 72(3) of the Rules of Procedure, the Committee consists of a chairman, a deputy chairman and five members. On 29 January 2010, Hon Alan LEONG Kah-kit and Hon WONG Yuk-man resigned from office as Legislative Council Members and ceased to be members of the Committee on the same day. On 26 February 2010, Hon Ronny TONG Ka-wah and Hon Cyd HO Sau-lan were elected by the House Committee and appointed by the President of the Legislative Council to fill the vacancies in the membership of the Committee.

4. The Committee wishes to thank Hon Alan LEONG Kah-kit and Hon WONG Yuk-man for their efforts and contributions in the Committee's examination of the chapter covered in this Report while they were members of the Committee. Hon Cyd HO Sau-lan and Hon Ronny TONG Ka-wah did not participate in the study of the chapter covered in this Report, or the preparation of this Report.

The Committee's Procedure The practice and procedure, as determined by the Committee in accordance with Rule 72 of the Rules of Procedure, are as follows:

(a) the public officers called before the Committee in accordance with Rule 72 of the Rules of Procedure, shall normally be the Controlling Officers of the Heads of Revenue or Expenditure to which the Director of Audit has referred in his Report except where the matter under consideration affects more than one such Head or involves a question of policy or of principle in which case the relevant Director of Bureau of the Government or other appropriate officers shall be called. Appearance before the Committee shall be a personal responsibility of the public officer called and whilst he may be accompanied by members of his staff to assist him with points of detail, the responsibility for the information or the production of records or documents required by the Committee shall rest with him alone;

(b) where any matter referred to in the Director of Audit's Report on the accounts of the Government relates to the affairs of an organisation subvented by the Government, the person normally required to appear before the Committee shall be the Controlling Officer of the vote from which the relevant subvention has been paid, but the Committee shall not preclude the calling of a representative of the subvented body concerned where it is considered that such a representative could assist the Committee in its deliberations;

(c) the Director of Audit and the Secretary for Financial Services and the Treasury shall be called upon to assist the Committee when Controlling Officers or other persons are providing information or explanations to the Committee;

(d) the Committee shall take evidence from any parties outside the civil service and the subvented sector before making reference to them in a report;

(e) the Committee shall not normally make recommendations on a case on the basis solely of the Director of Audit's presentation;

(f) the Committee shall not allow written submissions from Controlling Officers other than as an adjunct to their personal appearance before the Committee; and

(g) the Committee shall hold informal consultations with the Director of Audit from time to time, so that the Committee could suggest fruitful areas for value for money study by the Director of Audit.

2. **Confidentiality undertaking by members of the Committee** To enhance the integrity of the Committee and its work, members of the Public Accounts Committee have signed a confidentiality undertaking. Members agree that, in relation to the consideration of the Director of Audit's reports, they will not disclose any matter relating to the proceedings of the Committee that is classified as confidential, which shall include any evidence or documents presented to the Committee, and any information on discussions or deliberations at its meetings, other than at meetings held in public. Members also agree to take the necessary steps to prevent disclosure of such matter either before or after the Committee presents its report to the Council, unless the confidential classification has been removed by the Committee.

3. A copy of the Confidentiality Undertakings signed by members of the Committee has been uploaded onto the Legislative Council website.

4. **The Committee's Report** This Report contains the Public Accounts Committee's supplemental report on Chapter 5 of Report No. 53 of the Director of Audit on the results of value for money audits which was tabled in the Legislative Council on 25 November 2009. Value for money audits are conducted in accordance with the guidelines and procedures set out in the Paper on Scope of Government Audit in the Hong Kong Special Administrative Region - 'Value for Money Audits' which was tabled in the Provisional Legislative Council on 11 February 1998. A copy of the Paper is attached in ***Appendix 2***. The Committee's Report No. 53 was tabled in the Legislative Council on 3 February 2010.

5. **The Government's Response** The Government's response to the Committee's Report is contained in the Government Minute, which comments as appropriate on the Committee's conclusions and recommendations, indicates what action the Government proposes to take to rectify any irregularities which have been brought to notice by the Committee or by the Director of Audit and, if necessary, explains why it does not intend to take action. It is the Government's stated intention that the Government Minute should be laid on the table of the Legislative Council within three months of the laying of the Report of the Committee to which it relates.

Meetings The Committee held a total of seven meetings and two public hearings in respect of the subject covered in this Report. During the public hearings, the Committee heard evidence from a total of nine witnesses, including one Director of Bureau and four Heads of Department. The names of the witnesses are listed in ***Appendix 3*** to this Report. A copy of the Chairman's introductory remarks at the public hearing on 8 December 2009, which was the first in the series of public hearings held by the Committee relating to the Director of Audit's Report No. 53, is in ***Appendix 4***.

2. **Arrangement of the Report** The evidence of the witnesses who appeared before the Committee, and the Committee's specific conclusions and recommendations, based on the evidence and on its deliberations on the relevant chapter of the Director of Audit's Report, are set out in Part 4 below.

3. The audio record of the proceedings of the Committee's public hearing is available on the Legislative Council web site for the public to listen to.

4. **Acknowledgements** The Committee wishes to record its appreciation of the cooperative approach adopted by all the persons who were invited to give evidence. In addition, the Committee is grateful for the assistance and constructive advice given by the Secretary for Financial Services and the Treasury, the Legal Adviser and the Clerk. The Committee also wishes to thank the Director of Audit for the objective and professional manner in which he completed his Reports, and for the many services which he and his staff have rendered to the Committee throughout its deliberations.

A. Introduction

The Audit Commission ("Audit") conducted a review on the control of western medicines, with the objective of examining the adequacy of the Department of Health ("DH")'s work in the control of the trade and medicines. Audit found that there were inadequacies in the following areas:

- importation of unregistered medicines;
- inspection of dealers' activities and other enforcement actions;
- medicine testing, recalls and public alerts;
- licence-refusal criteria, prosecutions and disciplinary actions; and
- public information and internal support.

2. **Dr York CHOW Yat-ngok, Secretary for Food and Health**, made opening statements at the Committee's public hearings held on 15 December 2009 and 8 February 2010, the full text of which is in ***Appendices 5 and 6*** respectively.

B. Review of existing regulatory control of medicines and importation of unregistered medicines

Importation of unregistered medicines for re-export purposes

3. The Committee noted that if medicines were not properly regulated, Hong Kong people would be exposed to health and safety risks. As reported in paragraph 2.2 of the Director of Audit's Report ("Audit Report"), the sale of unregistered medicines in Hong Kong had become a growing public concern, and since February 2008, 79 patients had been affected by unregistered virility products and three had died.

4. Moreover, the Committee noted that the DH issued a large number of import licences ("ILs") a month to licensed traders for importing medicines for re-export purposes which were not required to be registered. Unregistered medicines imported this way might pose a public health risk if they were distributed for sale or consumption locally. However, Audit found that the DH did not have adequate controls to track the movements of imported medicines for re-export purposes, as illustrated below:

- while the DH issued about 2,560 ILs/export licences ("ELs") a week, it only referred 18 ILs/ELs (or 0.7%) to the Customs and Excise Department ("C&ED") a week for post-shipment consignment checking;

- the DH did not require licensed traders to furnish any returns on medicine movements;

- the DH did not perform adequate checking on the licensed traders' poisons records to ensure completeness of recording; and

- licensed traders were not required under the Pharmacy and Poisons Ordinance (Cap. 138) ("PPO") to keep records of transactions for Part II poisons and non-poisons.

5. Against the above background, the Committee noted with concern the Administration's delay in plugging the control loophole which could allow the illegal sale in Hong Kong of unregistered medicines purportedly imported for re-export purposes. As reported in paragraphs 2.14 to 2.16 of the Audit Report, at a meeting of the Legislative Council ("LegCo") Panel on Health Services ("Health Panel") with the Pharmacy and Poisons Board ("Board") and a pharmaceutical trade association in February 1999 to discuss the control of unregistered medicines in Hong Kong, 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 to work closely with the pharmaceutical trade with a view to closing the loophole. In March 2000, the Health Panel was informed that the Board would implement a revised arrangement of regulating the importation of unregistered medicines for re-export purposes. However, the proposed arrangement was subsequently shelved and the Board decided to adopt an alternative control measure which would require legislative amendments. Despite the change, neither the Board nor the DH had informed the Health Panel of the subsequent developments. Moreover, for the nine years from 2001 to 2009, no progress had been made in the submission of legislative proposals to the LegCo.

6. Given that the Secretary for Food and Health had stated in his opening remarks on 15 December 2009 that the regime for the regulation and control of medicines had to strike a fine balance between regulation and avoidance of creating unnecessary burden on the trade, the Committee questioned:

- whether the Food and Health Bureau ("FHB") and the DH attached more importance to safeguarding the interest of the trade than protecting the health of Hong Kong people;

- about the reason for not submitting the legislative proposals to the LegCo to plug the loophole in the import and export control of medicines, and whether this was because the Administration had under-estimated the urgency of the matter; and

- whether the Administration would enact laws to step up the control of importation of unregistered medicines intended for re-export.

7. The **Secretary for Food and Health** and **Dr LAM Ping-yan, Director of Health**, responded that:

- the Administration had all along adopted a risk-based approach towards medicines control in Hong Kong and targeted its efforts at those medicines that had greater public health impact, such as dangerous drugs ("DDs") and poisons. The Administration also decided its work priority, including the introduction of legislative proposals, based on risk assessments;

- it was true that before the occurrence of a series of incidents involving unsafe and unregistered medicines in early 2009, the Administration did not see the urgency of and hence did not accord a high priority to the introduction of legislative amendments to enhance the import and export control of medicines. Instead, the DH exercised regulatory control and monitored the operation of dealers at the retail level by means of test purchases and inspections, etc. Such control measures were considered effective;

- in the wake of the incidents in early 2009, the Administration considered that there was a need to conduct a comprehensive review of the existing regime for the regulation and control of medicines. The Review Committee on Regulation of Pharmaceutical Products in Hong Kong ("Review Committee") was therefore established to undertake the review and it would make recommendations, among other things, on the need to amend existing laws; and

- the Administration had reviewed the efficiency and effectiveness of the current practice of checking the import and export records of medicines by manual means and was prepared to introduce an electronic system to perform such function. In introducing the system, the Administration would have to carefully examine the implementation details and the responsibility of the trade, etc.

8. According to paragraphs 2.10 and 2.11 of the Audit Report, as the DH had not put in place adequate controls to track the movement of imported medicines for re-export purposes, some unregistered medicines might have been distributed for sale or consumption in Hong Kong. The Committee asked:

- about the Administration's views on the seriousness of such a problem; and

- whether the C&ED could help to prevent the illegal diversion of medicines imported for re-export purposes into the local market.

9. The **Director of Health** stated that:

- from experience, most of the unregistered medicines sold in the local market as seized by the DH during inspections were not imported into Hong Kong systematically under ILs. Instead, they were usually brought into Hong Kong on a small-scale and piecemeal basis. Such medicines included virility products which were more expensive; and

- heavy penalty would be imposed on licensees convicted of offences related to unregistered medicines. For instance, a listed seller of poisons ("LSP") would be removed from the List of LSPs and a disciplinary inquiry against an authorised seller of poisons ("ASP") would be held for first-time convictions involving illegal possession or sale of unregistered medicines.

10. **Mr CHEUNG Sai-yan, Head of Trade Controls of the C&ED**, said that the C&ED conducted customs control of the medicines imported and exported to check if they were covered by proper ILs and ELs. However, in case there were discrepancies in the quantity of medicines imported and re-exported, the C&ED would have difficulty in tracking the whereabouts of the medicines. It would have to work together with the DH in this respect.

11. To ascertain whether the DH had allocated sufficient resources to exercise import and export control of unregistered medicines, the Committee asked the Chief Pharmacist of the DH whether the DH had deployed sufficient manpower to carry out duties in this regard.

12. **Mr Anthony CHAN, Chief Pharmacist of the DH**, responded that there were currently 38 pharmacist inspectors ("PIs") who were responsible for inspections, test purchases, prosecutions, disciplinary inquiries and so on. 10 of them were only deployed to perform such duties recently. While the DH would make the best use of the available staffing resources, it would be more efficient to trace the whereabouts of imported and exported medicines through electronic means. The DH was considering the development of an electronic record system to facilitate the tracing and tracking of imported medicines intended for re-export.

Use of computer system to track movements of unregistered medicines

13. Regarding the DH's current plan to develop an electronic record system to help tracking medicines imported for re-export purposes, the Committee noted from paragraph 2.18 of the Audit Report that back in 1999, a pharmaceutical trade association had already suggested that the Government should consider devising a computer system, similar to the TradeNet System in Singapore, to monitor the import and export of medicines. The Committee queried why the DH had not followed up the proposal at that time and only started to explore the option recently.

14. The **Director of Health** explained that:

- it was only a suggestion made by a pharmaceutical trade association in 1999 to computerise the monitoring system. Singapore was more advanced than Hong Kong in using information technology ("IT") in import and export control. It was the Administration's intention at that time to make legislative amendments to require 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. Computerisation of the system was not an option to be explored. Instead, preparatory work on the legislative amendments was undertaken. Unfortunately, as it transpired, the legislative amendments did not materialise; and

- the Board took a serious view of the sale of unregistered medicines. In the past 10 years, it had raised the penalty imposed on LSPs and ASPs convicted of offences related to unregistered medicines.

15. In response to the Committee's request, the **Director of Health** provided, in his letter of 22 January 2010 in ***Appendix 7***, the number of convictions related to unregistered medicines and the penalties imposed by the courts in 2007, 2008 and 2009, as well as the policy of the Board in relation to ASPs and LSPs convicted of offences related to unregistered medicines before and after November 2000.

16. The Committee pointed out that Hong Kong people expected all medicines marketed in Hong Kong, including those distributed by medical practitioners and sold in ASPs, were properly registered and safe, and they relied on the Government to safeguard the safety and quality of medicines. The Committee queried whether:

- the DH had under-estimated the seriousness and impact of the sale of unregistered medicines in Hong Kong;

- the DH had chosen to address the problem by raising the penalty but not legislative means or computerisation because it was easier to implement the former course of action;

- some importers/exporters had resisted the computerisation of the record keeping system because it would be easier to escape the Administration's monitoring under a manual system; and

- after the Administration decided not to pursue the proposed legislative amendments, whether the DH had ever considered developing a computer system or making use of IT to enhance the control of medicines imported for re-export.

17. The **Director of Health** responded that:

- it was highly unlikely that unregistered medicines would be sold by medical practitioners. Most ASPs were law-abiding although there were indeed cases of ASPs selling unregistered medicines. For those cases, the unregistered medicines were not imported into Hong Kong in an organised manner under ILs. They were usually carried in small quantities by people travelling across the border and hence were difficult to be detected by the C&ED staff at the ports of entry;

- to address the problem, the DH educated the public about medicine safety. For instance, the DH emphasised that members of the public should not buy "prescription-only" medicines without prescriptions. The DH also provided information on ways to distinguish registered and unregistered medicines and the list of registered medicines through the department's website. The DH would improve its website to provide more information to the public; and

- in 1999 and 2000, the DH had not considered devising a computer system even though the proposed legislative amendments were not pursued.

18. The **Chief Pharmacist** added that:

- in 1999, the suggestion of devising a computer system to monitor the import and export of medicines was raised by a pharmaceutical trade association during an informal meeting between it and some Board members. Members of that trade association were large multi-national companies and more advanced in their operation; and

- the suggestion was opposed by small to medium size pharmaceutical importers/exporters because many companies did not use computers in their day-to-day operations in those days. To require them to use computers to submit IL and EL applications would create operational difficulties. In view of the trade's practical difficulties, the suggestion was considered not feasible and not followed up at that time.

Impact of inadequacies in control

19. The Committee referred to the results of Audit's checking of 15 ILs, as detailed in paragraph 2.12(d) of the Audit Report, in which 10 ILs were found to have irregularities. The results indicated that some of the medicines concerned might have been sold locally instead of being re-exported. Given that a large proportion of the ILs checked by Audit had irregularities, the Committee:

- queried why the Director of Health considered it unlikely for medicines purportedly imported for re-export to be diverted into the local market despite the lack of control in this regard; and

- asked about the details of the risk-based approach adopted by the Administration.

20. The **Director of Health** explained that:

- of the 10 ILs identified by Audit to have irregularities, not many of them had public health impact. There were three ILs that involved improper sales of imported medicines locally instead of re-export. As a matter of fact, some of the medicines concerned were registered ones and the DH would have allowed them to be sold locally if the dealers had applied to do so. For instance, there was one IL involving the importation of 8,000 vials of a medicine (containing Part I poisons) and 911 vials were delivered to another licensed dealer for local sale three weeks after importation. For this case, the DH would have allowed the medicine to be imported for local consumption if an application had been made. Although some vials of the medicine were sold locally instead of being re-exported, this was only a technical error and did not pose risk to public health;

- some ILs involved imported medicines having been held in stock for a long time. The Import and Export Ordinance (Cap. 60) did not specify any time limit within which the imported medicines had to be re-exported. The medicines being held in stock for a long time might be disposed of upon expiry of their validity period. For those ILs involving short shipments in the importation of medicines and re-export of medicines to countries other

than that declared on the licences, the dealers concerned did not breach the legal requirements; and

- regarding the case in which the dealer, whose licence had been revoked, was suspected of illegally possessing Part I poisons, prosecution should be taken.

21. Regarding the risk-based approach for the control of medicines, the **Director of Health** said that:

- there were currently some 1,100 importers, exporters and wholesalers in Hong Kong and a large number of drug items and traders subject to regulation. Under such circumstances, the Administration had to adopt a risk-based approach in controlling and regulating medicines and target its efforts at those that were more hazardous and had greater impact on public health;

- in the order of risk to public health, DDs were accorded the strictest control, followed by Part I poisons. Part I poisons were required to be sold under the supervision of registered pharmacists, with the support of prescriptions by registered medical practitioners. Part II poisons and non-poisons were accorded a lower level of control. Part II poisons included medicated shampoo and vitamins, which could be sold without the supervision of registered pharmacists;

- about 70% of the ILs/ELs issued by the DH were for Part I poisons and DDs. The majority of such medicines were unregistered and would not be used by Hong Kong people. It was therefore not common for Part I poisons imported for re-export purposes to be diverted illegally for sale in Hong Kong. On the other hand, as dealers were not required by law to keep transaction records of Part II poisons, occasionally there were cases of unregistered Part II poisons being sold in some ASPs. Yet, Part II poisons were of low risk; and

- if dealers were required to maintain complete transaction records of Part II poisons, the DH would be able to conduct checking of the records. To implement the tightened requirement, however, the DH would need more manpower to conduct checking and the dealers' cost of business would also increase. Hence, when considering the introduction of a new regulatory requirement, the Administration had to take into account the trade's ability to comply with it and strike a proper balance. While public health was the Administration's primary concern, it was also important that a new regulatory requirement was reasonable. As recommended by Audit, in devising measures to strengthen import control, the Administration should be mindful not to create cumbersome procedures which might cause inconvenience to the

trade and discourage business (paragraph 2.20(c) of the Audit Report referred).

Report of the Review Committee ("Review Report")

22. In his letter of 22 January 2010, the **Director of Health** provided to the Committee a copy of the Review Report. At the Committee's public hearing held on 8 February 2010, the **Secretary for Food and Health** informed the Committee that:

- the Review Report contained a total of 75 recommendations. One of the recommendations was targeted at the diversion of pharmaceutical products imported for re-export purposes into the local market. It was recommended in the Review Report that the control and tracking of the import and export of such products should be strengthened, including the setting up of a record and tracking system to require EL applicants to produce the relevant import licences. This would enable staff of the DH to keep track of the amount imported and exported to prevent illegal diversion of drugs imported for re-export purposes into the local market;

- the Review Report also recommended stepping up the regulation of importers/exporters, wholesalers and retailers, including strengthening the licensing system, introducing new licensing conditions and requiring traders to keep all transaction records as well as introducing a code of practice. In implementing such recommendations, the Administration would conduct full consultation with members of the trade in an effort to minimise the inconvenience caused to them;

- another recommendation was the setting up of a new dedicated office on drugs to strengthen the regulatory role of the Government in enhancing drug safety. The office would formulate plans on drug regulation and direct the implementation of various measures relating to drug safety. In the long run, consideration would be given to expanding the office to become a "Centre for Drug Safety"; and

- the Government would take follow-up actions to implement the measures recommended in the Review Report. The FHB would take charge of the policy issues and, together with the DH, study the legislative amendments required and address the resource implications involved. The implementation of some recommendations of the Review Committee required amendments to the existing PPO. The FHB and the DH would work with the Department of Justice ("DoJ") to prepare the legislative amendments. The trade and other stakeholders would be consulted before the legislative proposals were submitted to the LegCo.

23. In view of the Secretary for Food and Health's remarks that the Administration would conduct full consultation with members of the trade in implementing the Review Committee's recommendations, the Committee asked whether the Administration had the resolve to implement the recommendations in the interest of the public if traders objected to the proposals, such as on the ground that they were not used to using computers for record keeping.

24. The **Secretary for Food and Health** said that the 75 recommendations were put forth by the Review Committee after one year's discussions with the stakeholders. Although individual stakeholders might hold a different view on some recommendations, the majority of them supported the recommendations. The recommendation on the introduction of an electronic record system to facilitate the tracking of imported and exported medicines was made by the Review Committee having regard to the need to protect the interest of patients and the public. The Administration was committed to the development of the system to enhance the import and export control of medicines.

25. The Committee noted the Review Committee's observation that the weekly quota of 18 licences for post-shipment consignment checks was agreed between the C&ED and the DH in consideration of the workload of the C&ED staff. It also pointed out that the weekly quota had remained unchanged for many years while the numbers of ILs and ELs had been on an increasing trend in recent years. The Review Committee therefore recommended that the DH should conduct joint review with the C&ED to determine a new weekly quota which represented a statistically significant sample size of the ILs and ELs population.

26. The Committee noted that a number of recommendations of the Review Committee required legislative amendments and asked when the proposals would be submitted to the LegCo. The **Director of Health** replied that the DH was preparing the drafting instructions and hoped that the legislative amendments would be ready by early 2011.

C. Inspection of dealers' activities and other enforcement actions

Inadequacies in the DH's inspections

27. The Committee understood that before the medicine incidents in 2009, the Administration did not find it necessary to introduce legislative amendments to tighten up the import and export control of medicines, and it considered the DH's inspections and other enforcement actions at the retail level effective. Noting the many deficiencies revealed in Part 3 of the Audit Report, the Committee asked about the Administration's view on the effectiveness of the DH's inspections and enforcement actions.

28. The **Secretary for Food and Health** responded that although there were inadequacies in the DH's enforcement actions, the routine inspections carried out by the department were generally effective. His view was supported by the relatively small number of unregistered medicines sold in the local market throughout the years. Moreover, Hong Kong had a high standard of regulatory control of medicine safety at the retail level and hospital level.

29. The Committee noted from paragraph 3.35 of the Audit Report that Audit had made a number of recommendations on the measures to improve the DH's inspections and enforcement actions. However, the Director of Health's response in paragraph 3.36 gave an impression that he did not accept Audit's observations. The Committee asked whether this was the case.

30. The **Director of Health** responded that:

- as stated in paragraph 3.36 of the Audit Report, the DH welcomed Audit's recommendations and would take steps to implement the improvement measures. His response in that paragraph only sought to explain the different purposes of routine inspections and test purchases;

- routine inspections of ASPs and LSPs were conducted once or twice annually on each ASP and LSP with the aim of ensuring compliance with licensing conditions. The inspections covered compliance with regulations on the sale and storage of medicines, etc. Discovery of fraud was not the objective and the PIs would not search the premises of ASPs and LSPs for unregistered medicines during routine inspections; and

- for the purpose of detecting illegal sale of medicines by ASPs and LSPs, test purchases would be conducted. The DH would also improve the mode of conducting test purchases as recommended by Audit.

Frequency of inspections

31. The Committee noted from paragraph 3.20 of the Audit Report that as at 30 June 2009, there were 330 wholesalers and 106 importers/exporters whose premises had not been inspected for over one year. Paragraph 3.21 also stated that some wholesalers with convictions or poor performance had not been inspected more frequently. For example, although the wholesaler mentioned in Case 3 had past conviction records, 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).

32. The Committee further referred to paragraph 3.34 of the Audit Report which reported that the DH had not always inspected convicted ASPs on a more frequent basis, and the average rate of inspecting twice a year for such ASPs was not always achieved. The two ASPs mentioned in Appendix H of the Audit Report were examples.

33. The Committee queried why the DH was slack in its inspections and about the remedial actions that it would take to improve the situation. The **Director of Health** and the **Chief Pharmacist** responded that:

- the DH was not slack in its enforcement actions. On the contrary, it attached high importance to combating illegal sale of medicines. However, due to the need to deploy the PIs to handle crisis situations, the DH could not meet its target of inspecting a wholesaler's premises at least once a year;

- there was room for improvement in respect of Case 3. In fact, the DH had conducted inspections in July 2006, June and September 2007, and September 2009 in relation to the wholesaler's application for changes of licensing particulars. However, as commented by Audit, such inspections were not routine inspections and were not thorough enough; and

- it was indeed unsatisfactory that the DH could not achieve the required number of inspections in respect of the two ASPs mentioned in Appendix H of the Audit Report. On the whole, however, the DH could achieve the average rate of inspecting ASPs twice a year. The DH would review its work process and procedures to ensure that convicted ASPs were inspected more frequently.

Site inspections outside Hong Kong

34. Paragraph 3.10(a) of the Audit Report revealed another deficiency in the DH's inspections, i.e. although some manufacturers had outsourced their manufacturing to contractors outside Hong Kong, the DH had not conducted any inspections of the premises of such contractors. The Committee asked whether the DH would conduct inspections of outsourced contractors' premises outside Hong Kong to ensure the quality of medicines produced by them.

35. The **Director of Health** and the **Chief Pharmacist** replied that:

- the Review Committee recommended that for medicines of other places without recognised Good Manufacturing Practice ("GMP") certificates, their manufacturing premises had to be inspected by either the DH's PIs or a third party approved by the Board to certify that their GMP standards were equivalent to the Pharmaceutical Inspection Co-operation Scheme standards before they would be allowed to import into Hong Kong. Additional staff would be required to implement the recommendation and the DH was actively studying the proposal; and

- the proposed requirement was in line with overseas practice. For example, in Australia, the manufacturer was required to provide acceptable evidence of GMP compliance for the contractors' premises and, if this was not available, inspections of the overseas manufacturers/contractors' premises would be arranged. The cost would be borne by the manufacturer.

Test purchases

36. According to paragraph 3.30 of the Audit Report, while only ASPs and LSPs were allowed to sell poisons, Audit was successful in test purchases of Part II poisons in 17 unlicensed retail shops during March to August 2009. The Committee asked:

- whether the DH had taken follow-up actions on such cases; and

- why the DH had not taken enforcement actions against the 17 unlicensed retail outlets before, and whether this was because of manpower shortage.

37. The **Chief Pharmacist** replied that:

- the DH had prosecuted the 17 unlicensed retail shops based on the information provided by Audit and the DH's test purchase results. Some of them were already convicted and fined;

- the DH's enforcement actions were targeted at licensed retailers, i.e. ASPs and LSPs, and illegal sales of Part I poisons because such medicines could cause greater impact on public health. In the past, the DH seldom conducted searches in respect of unlicensed retail outlets; and

- the DH had begun to conduct test purchases from unlicensed retail shops. Test purchases were not performed by PIs but by casual workers acting as customers to purchase some medicines that the shops were not licensed to sell. There should be sufficient manpower to perform the work.

38. The **Director of Health** supplemented that the medicines sold in unlicensed retail outlets were mostly influenza medicines, which were of low risk. In view of Audit's concern, the DH would conduct test purchases from such outlets. Although PIs did not conduct test purchases, they were involved in follow-up and prosecution actions. Therefore, it was necessary to prioritise the focus of their work.

39. The **Secretary for Food and Health** said that:

- the Administration supported the DH's inspection strategy of focusing its efforts on high-risk medicines, i.e. Part I poisons, as they would cause greater adverse impact on patients if taken improperly; and

- he agreed with Audit's recommendation that the DH should conduct more test purchases from retail outlets. If there were more prosecution cases of illegal sales of medicines and heavier penalties, a strong message could be sent to the public that they should not purchase medicines from improper outlets. He also agreed that the DH should launch more publicity programmes to increase public knowledge of medicines.

40. The Committee noted that the DH had accepted Audit's recommendations on ways to improve its mode of conducting test purchases, as set out in paragraph 3.46 of the Audit Report. The Committee asked about the progress and effectiveness of the new arrangements since the publication of the Audit Report in late November 2009, including the proposal of purchasing different medicines at different times and different places based on risk assessment.

41. In his letter of 11 March 2010 in ***Appendix 8***, the **Director of Health** informed the Committee that:

- the DH had reviewed the protocol of test purchases. Since December 2009, the DH had implemented a programme to conduct night-time and weekend test purchases, on top of the usual test-purchases conducted during office hours. Medicines chosen for night-time and weekend test purchases were those likely to be sold at such times, such as sleeping pills and cough medicines. Areas throughout Hong Kong where business hours ran late were specially targeted at. In addition, seasonal tactics had also been adopted. For example, operations to combat over-the-counter sale of post-coital contraceptive pills were conducted in December 2009 and early January 2010, to coincide with the festive periods of Christmas and New Year. Data were being consolidated for the purpose of reviewing the effectiveness of the new measures; and

- apart from retail shops, sales on the Internet had also been targeted at. Test purchases for suspected products were conducted, both routinely and as a part of investigations. Such test purchases had resulted in a number of public alerts which, among other things, served to exhort people not to buy or sell products of unknown or doubtful composition.

Penalty system

42. The Committee referred to Case 2 in paragraph 3.10(b) of the Audit Report concerning a manufacturer with poor performance and conviction records. 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. Given that the penalties imposed appeared to be too lenient to have any deterrent effect, the Committee enquired whether the DH:

- considered that the penalties imposed by the court were proportionate to the seriousness of the offences concerned; and

- had requested the court to review the penalties.

43. The **Director of Health** and the **Chief Pharmacist** said that:

- generally speaking, the level of penalties imposed by the court was far below that expected by the DH. The DH had a mechanism of reviewing the penalty for each case. Where warranted, the DH would, through the DoJ, request the court to review and increase the penalty. However, sentencing in any individual case was at the discretion of the court; and

- regarding Case 2, the DH had not requested a review of the penalties because the offences were not very serious. For the offence in February 2004, the unregistered medicine concerned was originally registered, but the colour of its capsule was changed without approval of the Board. As such, it became an unregistered medicine and the manufacturer was prosecuted for selling it to an ASP. Under the PPO, the sale of an unregistered medicine was an offence carrying a maximum penalty of $100,000 and two years' imprisonment. In this case, the manufacturer was fined $3,000. For the offence in July 2005, the manufacturer inadvertently sold DDs to a non-registered medical practitioner who used the DDs for treatment of patients.

44. In response to the Committee's questions about the specific recommendations of the Review Committee regarding the penalty system under the PPO, the **Director of Health** said that:

- the Review Committee considered that the current maximum penalty of $100,000 fine and two years' imprisonment imposed by the PPO sufficient for summary convictions of the offences in the PPO, and at present it was inappropriate to amend the PPO to raise the maximum penalty. On the other hand, the Review Committee noted that based on past conviction records, 60% of the penalty imposed by the court in recent years were on the low end of $5,000 or below;

- the recommendations of the Review Committee on enhancement of the penalty system included:

  (a) for prosecution cases, the DH should include more aggravating factors in the facts submitted to the court to reflect the seriousness of the offence concerned for the court to consider the imposition of a penalty proportionate to the seriousness of the offence. As a first step, the DH would track the sentencing of the court by gathering the data on the sentencing of each case after implementation of the enhancement strategies with a view to identifying any further weaknesses of the current law for review of the maximum penalty at the next stage; and

  (b) as the cost for analysing exhibits in court cases could be substantial, the law should be amended to require the convicted person to bear such costs in order to increase the deterrent effect; and

- in addition, at present the Board could only stop renewing the licences of ASPs at the beginning of each year, but had no authority to revoke the licences during the year. The Review Committee had recommended giving such authority to the Board so that the licence of an ASP could be revoked immediately if it had committed a serious offence.

Manpower requirements of the DH

45. In response to the Committee's question as to whether the DH had sufficient manpower to monitor illegal sale of medicines by unlicensed retail outlets, the **Chief Pharmacist** said that the different units and divisions of the department all faced increased workload and enhanced public expectation and required more resources. The Pharmaceutical Service, as a unit of the department, understood the real situation as well as the department's policy and arrangements in deploying resources. It had tried its best to carry out its assigned duties with given resources.

46. To ascertain whether the DH had addressed the manpower demand of the Pharmaceutical Service, the Committee requested the Chief Pharmacist to provide a list of the suggestions that he had made in the past 10 years to step up the import/export and other control of medicines, including manpower requests and proposals to amend legislation, as well as the department's response.

47. The **Chief Pharmacist** informed the Committee, vide Annex 2 of the Director of Health's letter of 22 January 2010, that his suggestions were as follows:

- seeking the agreement of the DH not to reduce the number of staff involved in inspection and prosecution duties when the Government implemented the Enhanced Productivity Programme in 1999-2003. The proposal was accepted by the DH;

- excluding the Pharmacist grade, which formed the backbone for undertaking inspection and prosecution duties, from the two rounds of Voluntary Retirement Schemes in 2000 and 2003. The proposal was accepted by DH;

- tightening up post-conviction actions against licensed retailers by the Board in respect of convictions involving unregistered medicines: instead of a warning, a disciplinary inquiry to be held against convicted ASPs, and licence removal against convicted LSPs. The proposal was implemented in November 2000. As a result, from 2001 to 2009, 49 ASPs were convicted, in which 22 had their licence suspended, and 50 LSPs were convicted, in which 27 had their licence removed;

- amending legislation to require importers to keep full transaction records of unregistered medicines imported for the purpose of re-export, to submit copies of the same to the Board as and when required, and to make them available for inspection on site as and when required. The proposal was agreed by the Board and submitted to the then Health, Welfare and Food Bureau in February 2001. It subsequently transpired that, as per legal advice received from the DoJ, amendment of the principal ordinance would be required in addition to amendment of the subsidiary legislation; and

- making submissions to strengthen manpower provision to enhance the control of medicines.

48. The **Secretary for Food and Health** said that the Administration was prepared to allocate more resources to the Pharmaceutical Service with a view to raising the standard of control of medicines. One of the Review Committee's recommendations was to expand the Pharmaceutical Service into a dedicated office on drugs to strengthen the DH's regulatory role in enhancing drug safety and to expanding the office to be a "Centre for Drug Safety" in the long run. The Review Committee had also addressed the manpower requirements of the Pharmaceutical Service in implementing the recommendations.

49. In response to the Committee's enquiries about the additional staffing resources required for implementing all the recommendations in the Review Report and the timetable for obtaining the resources, the **Secretary for Food and Health** and the **Director of Health** said that the Review Committee had recommended an addition of about 160 posts, and detailed implementation plans were given in the Review Report.

50. In his letter of 11 March 2010, the **Director of Health** further informed the Committee that:

- immediately after the medicine incidents in March 2009, three contract Pharmacists were recruited to enhance the regulatory control of pharmaceutical products. This was followed by 10 additional Pharmacists in May 2009, making a total of 13 contract Pharmacists; and

- subject to the approval of the 2010-2011 draft Estimates by the LegCo, the DH planned to create new posts of 10 Pharmacists and 1 Scientific Officer specialised in microbiology to further strengthen the regulation of pharmaceutical products. Further resources, if required, for implementing the various tasks set out in the Review Report would be sought according to established procedures.

D. Medicine testing, recalls and public alerts

Testing of medicine samples collected from manufacturers' premises

51. According to paragraph 4.11 of the Audit Report, 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. On the other hand, paragraph 4.14 revealed that in 2009, after the occurrence of the medicine incidents, there were great improvements overall. For the quarter ended June 2009, the time lag was only 26 days and 9 days respectively.

52. Against the above background, the Committee asked whether the slow action in delivering samples to the GL and in collecting test results was due to the DH's according a low priority to this area of work or laziness on the part of the staff concerned.

53. The **Secretary for Food and Health** and the **Director of Health** responded that:

- there was no question of laziness on the part of staff. Sample testing on products collected from different sources was risk-based. Samples collected for investigations of complaints or medicine incidents were accorded the highest priorities. The GL would conduct testing on such samples urgently;

- some samples were collected during inspections of manufacturers' premises in connection with their annual licence renewal. As the purpose of conducting tests on such samples was to validate the results conducted by the manufacturers' laboratories, the impact of substandard test results was generally on quality instead of safety. Such tests were therefore given lower priorities. As the GL could only test about 4,500 samples per year, the DH had to spread the delivery of samples to the GL for testing over the year. Some samples were therefore kept in the DH's office pending delivery to the GL;

- the long time lag in collecting test results did not delay the taking of necessary follow-up actions, e.g. recall actions, by the DH. There was an agreement that 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. Yet, the Administration agreed that the current long time lag was unsatisfactory. To improve the situation, the DH was exploring with the GL the feasibility of using IT to monitor the movement of samples and disseminate test results; and

- it was agreed that the current arrangements for testing of medicine samples should be improved. In this connection, the DH was consulting the GL on ways to speed up the testing of medicine samples, including the setting of performance targets for the turnaround time of sample testing. Consideration would also be given to outsourcing the routine testing work to laboratories in the private sector. This could release the GL's resources to focus on urgent cases or samples which would be used as court evidence. The Administration would report the progress made in this regard to the Health Panel.

54. **Dr LAU Chau-ming, Acting Government Chemist of the GL**, said that:

- a longer turnaround time was necessary for some medicine samples because of the time taken to verify testing methods and purchase reference materials. The turnaround time for the testing could range from a few to over 100 days; and

- following the adoption of the streamlined procedures by the DH since 2 January 2009, post-registration tests could be completed with a shorter turnaround time. As a result, the GL's annual test workload of 4,500 samples could be increased.

Medicine recalls

55. The Committee noted from paragraph 4.20 of the Audit Report that the DH had no procedures to require manufacturers/wholesalers to recall medicines with expired registration, and Audit found that two medicines with expired registration were still available for sale in the market. In addition, paragraph 4.21 reported that the DH did not have guidelines to assist PIs in making decisions on when they should request manufacturers/wholesalers to take recall actions. For instance, in Case 5, the PI did not ask the wholesaler to recall a substandard medicine the registration of which had expired. The Committee queried whether the DH:

- had been perfunctory in monitoring medicine recall action, as a result of which the recall actions were not effective;

- considered the PI's decision in Case 5 correct; and

- had taken any improvement measures.

56. The **Chief Pharmacist** responded that:

- when the registration of a medicine was about to expire, the DH would send letters to the manufacturer/wholesaler concerned to remind him to renew the registration or the medicine would become unregistered and not allowed to be sold. In the past, however, it was not stated in the letters that the manufacturer/wholesaler had to recall the medicine upon the expiry of the registration. Starting from the third quarter of 2009, the DH had specified such requirement in the letter;

- regarding Case 5, it was unfortunate that the PI concerned did not recall the medicine because its registration had expired in February 2008 and the wholesaler did not renew the registration. In such circumstances, the PI thought that it was not necessary to recall the medicine. The decision was wrong. The PI concerned had been given an informal verbal warning; and

- the DH had reminded all responsible staff that in case a medicine failed in the GL test, it had to be recalled irrespective of whether its registration was still valid.

57. In response to the Committee's enquiry about the actions taken by the DH to ensure the recall of medicines with expired registration, the **Director of Health** stated in his letter of 11 March 2010 that:

- each time the registration of a medicine expired and was not renewed, the DH issued a notification to the manufacturer or importer concerned, with a specific instruction to recall the medicine; and

- the DH also put the name of the medicine on the inspectors' watch list. During inspections at drug dealers' premises, the inspectors would pay particular attention to ensure that the medicine was no longer available for sale.

58. The Committee further referred to paragraph 4.24 of the Audit Report which revealed that out of the 30 recall reports examined by Audit, 16 did not provide adequate information on the recall details while the remaining 14 showed that the percentage of medicines recalled were generally very low. However, the DH had not taken any follow-up actions. It appeared to the Committee that the DH did not accord a high priority to this area of work although it was an integral part of the regulatory regime to ensure the safety of medicines. The Committee asked about the reasons for the low recall rates and the actions that the DH would take to improve the situation.

59. The **Director of Health** and the **Chief Pharmacist** said that:

- the recall reports did not contain detailed information because at present the law only required wholesalers to keep transaction records for Part I poisons. There were no similar requirements for Part II poisons or non-poisons. As a result, the wholesalers might not maintain detailed records on the transaction of Part II poisons and non-poisons, thus creating difficulties in the event of a medicine recall;

- the Review Committee considered the situation undesirable and recommended that wholesalers should be required to keep transaction records for all pharmaceutical products, including Part II poisons and non-poisons. This would enable the wholesalers to trace the whereabouts of the medicines concerned and recall the medicines comprehensively when problems arose. To implement the recommendation, the existing legislation would have to be amended. The enhanced control of Part II poisons and non-poisons, which included common medicines like pain-killers, would affect the trade and the public, e.g. the dealers for such medicines might have to be licensed and the retail outlets might be reduced, making it more inconvenient for members of the public to buy them. The DH would have to strike a balance when introducing the relevant legislative proposal;

- as stated in paragraph 4.24(b), for those recall reports with details of recalls, the percentage of medicines recalled were very low. This was because a wholesaler might have sold the medicine to retailers who, in turn, sold the medicine to customers. Some of the medicine might have been consumed. At present, when a medicine failed in the GL test, the DH would issue public alerts to notify the public not to consume the medicine as it was found defective, but the department would not require the public to return it;

- as there were a large number of retail outlets, particularly those selling non-poisons, it would be very difficult for the DH to conduct inspections at retail outlets to ascertain whether the medicines with low recall rates were still available in the market. It was in fact the responsibility of the manufacturers and wholesalers to recall a medicine. Nevertheless, the DH had enhanced the monitoring of recall actions; and

- as an improvement, the Review Committee recommended that the DH should include a refund mechanism in its recall guidelines to require manufacturers and wholesalers to provide refund details to consumers at the retail level in the event of medicine recalls. This would provide incentive to the customers who had bought the defective medicines to return the unused medicines to the retailers. The DH was studying the recommendation.

60. According to paragraph 4.25 of the Audit Report, the DH had tightened up the recall actions from April 2009 onwards. The Committee enquired about the details of the DH's actions and their effectiveness.

61. The **Director of Health** informed the Committee in his letter of 11 March 2010 that:

- since March 2009, the DH had enhanced its monitoring of recalls conducted by manufacturers and importers. For each recall, the company concerned was instructed to submit to the DH a detailed distribution list of the product concerned. The distribution list contained the following information:

  (a) the name of the medicine and batch number to be recalled;

  (b) the date the batch began to be distributed;

  (c) the batch size of the medicine;

  (d) the quantity of the medicine not yet distributed;

  (e) the name of each institution to whom the medicine had been distributed; and

  (f) the quantity of the medicine distributed to each institution and the total quantity distributed;

- after the recall was completed, the manufacturer/wholesaler should submit to the DH a report listing out the quantity of the medicine recalled from each institution and the total quantity recalled. Officers of the DH inspected some of the institutions on a risk-based approach (e.g. those who had obtained a large quantity of the medicine) to check if the medicine had been effectively recalled; and

- between March and December 2009, there were 10 recalls and about 100 institutions were inspected to follow up on the effectiveness of the recalls. None of the institutions was found to be still in possession of the recalled medicine. This demonstrated that the enhanced monitoring mechanism was effective.

Public alerts

62. The Committee referred to Case 6 and Case 7 in paragraph 4.27 of the Audit Report which showed that the DH had not issued any public alert or the public alert was not issued promptly, and there was no documentation to support the DH's decisions of not issuing public alerts. The Committee asked for an explanation from the DH.

63. The **Director of Health** and the **Chief Pharmacist** explained that:

- it was a common practice of advanced countries, such as the United States and European countries, to classify drug safety hazards into different levels in accordance with the degree of risk, and then deploy the corresponding public alert strategies;

- for Case 6, the European Medicines Agency ("EMA") recommended the suspension of the marketing authorisation for a particular medicine across the European Union ("EU") because an EMA review of the medicine had found that the benefits of the medicine did not outweigh the risks of psychiatric reactions in clinical use. The medicine recall was only down to the retail level. Patients who were taking the medicine were not asked to stop taking it immediately, but were to be followed up by doctors. No public alert was issued. In this case, the DH followed the arrangements adopted by the EU and recalled the product from doctors, ASPs and hospitals, but not patients. Also, the DH did not issue a public alert;

- for Case 7, the DH did not issue a public alert in April 2008 because the health product concerned was not a registered medicine and was not sold in Hong Kong. The source of the product could not be identified and it was believed that some individuals had brought it into Hong Kong from the Mainland. As the product was not sold in Hong Kong or consumed by a large number of people, a public alert was not issued at that time. However, in April 2009, another patient was affected by the consumption of the same product. Given that the product had caused incidents twice, the DH decided to issue a public alert in May 2009; and

- in view of the expectation of Hong Kong people, the DH decided to adopt the practice of issuing a public alert whenever an incident had occurred.

E. Licence-refusal criteria, prosecutions and disciplinary actions

Enforcement of disciplinary actions

64. The Committee noted that some former LSPs were still continuing the retail sale of Part II poisons after their removal from the LSP list due to convictions. As shown in Case 8 in paragraph 5.12 of the Audit Report, subsequent to the revocation of Dealer 3's wholesale poisons licence in October 2008, the DH inspected his premises and found no poison kept. However, in September 2009, the DH seized 29 carton boxes of medicines belonging to Dealer 3. The Committee queried why the DH was not aware of the existence of the medicines at the time of its inspection in 2008.

65. The **Chief Pharmacist** said that:

- when the licence of an ASP/LSP was suspended or revoked, the PIs would inspect the premises of the ASP/LSP concerned to ensure that no poisons were kept in the premises; and

- regarding Case 8, the PIs had inspected the premises of Dealer 3 on the day following the licence revocation and no poison was found. The poisons subsequently found in his premises were probably purchased by him after the licence revocation. Any person who possessed Part I poisons or Part II poisons without a valid licence was in breach of the law. If there was sufficient evidence, the DH would refer the case to the DoJ for prosecution.

Effectiveness of licence-refusal criteria and disciplinary actions

66. According to paragraph 5.23 of the Audit Report, the licence-refusal criteria for ASPs were more relaxed than those for LSPs in that the former covered only convictions relating to psychotropic drugs, zopiclone or cough medicines. In comparison, the criteria for LSPs were broader as they covered all drug-related convictions. The Committee asked:

- about the rationale for adopting different licence-refusal criteria for ASPs and LSPs; and

- whether the DH would consider broadening the licence-refusal criteria for ASPs.

67. The **Director of Health** explained that:

- ASPs were authorised to sell Part I poisons, Part II poisons and non-poisons. The law required that registered pharmacists should be present at the premises of ASPs to supervise the sale of poisons. LSPs were only allowed to sell Part II poisons and non-poisons, and they did not have the service of a registered pharmacist;

- the licence-refusal criteria for ASPs and LSPs were different because in the past, many ASPs were involved in offences relating to the sale of psychotropic drugs, zopiclone or cough medicines. But this was no longer a problem nowadays. The DH and the Board kept in view of changing circumstances and specify different drug offences in the licence-refusal criteria. The Board would refuse an ASP application if any of the persons involved had had two convictions in the past three years related to any specified drug offences; and

- the control of ASPs and LSPs had been tightened up. For instance, an ASP convicted of sale of forged medicines, even for the first time, would have its licence revoked, while an LSP would be removed from the List of LSPs. Moreover, the Review Committee had recommended giving the Board the authority to revoke the licence of an ASP at any time if the ASP concerned had committed a serious drug offence, as well as amending the law to the effect that a registered pharmacist should be present in an ASP whenever it was open for business.

68. The Committee enquired about the respective numbers of ASP and LSP licence applications approved and refused in the past three years. In his letter of 22 January 2010, the **Director of Health** provided the following information:

	ASPs		LSPs	
Year	No. of applications approved	No. of applications refused	No. of applications approved	No. of applications refused
2007	39	0	311	0
2008	35	0	572	1
2009	57	0	337	1

69. The **Director of Health** also stated in the same letter that the two cases in 2008 and 2009 were refused because the applicant concerned did not meet the established licensing requirements of any person involved in the ownership or operation of the applicant company having had one conviction related to unregistered medicines, drugs of abuse or counterfeit drugs in the past three years, or two convictions of other drugs in the past three years.

70. The Committee noted from paragraphs 5.27 to 5.30 of the Audit Report that there were ASPs who, after committing serious offences, closed business to escape punishment, but restarted business at the same premises as new ASPs. Case 9 was an example. Moreover, 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. The Committee asked how the DH would rectify the situation.

71. The **Director of Health** stated at the public hearings and in his letter of 11 March 2010 that:

- under the existing licensing requirements, in assessing an ASP application, the Board would take into consideration the conviction records of the applicant and the personnel of the ASP concerned, but not the convictions in related ASPs; and

- the DH had consulted the DoJ on Audit's proposal of taking into account convictions in related ASPs when assessing applications for ASP registration. The advice received would be considered by the Board.

F. Public information and internal support

72. The Committee noted that the DH had computerised many of its manual records, but there were inadequacies in its record keeping, which might have significantly affected its operational efficiency. As stated in paragraph 6.9 of the Audit Report, the DH spent $11 million in developing five computer systems and needed $1.7 million a year for maintaining them. However, according to paragraph 6.10(a), important operational data were not timely updated to the computer systems, with many computer functions not having been used. The Committee enquired about the actions that the DH would take to ensure that the systems would be put to beneficial use.

73. The Committee further referred to paragraph 6.13 in which the Director of Health had said that the DH would review the existing supporting system and take steps to upgrade it when the required resources were available. The Committee asked about the timetable for upgrading the system.

74. The **Secretary for Food and Health** responded that:

- the DH had been making use of computer systems in various aspects of its work, including the registration and monitoring of pharmaceutical products. But some systems, like those for tracing the whereabouts of medicines, required the cooperation of dealers; and

- the Review Committee had recommended widening the use of IT and computer systems in drug handling. For example, it recommended that the DH should upgrade its central inventory monitoring computer system to enhance the traceability of drugs in four years' time.

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.

SIGNATURES OF THE CHAIRMAN, DEPUTY CHAIRMAN, AND MEMBERS OF THE COMMITTEE WHO ARE INVOLVED IN THE EXAMINATION OF THE CHAPTER COVERED IN THIS REPORT

Philip WONG Yu-hong
(Chairman)

Paul CHAN Mo-po
(Deputy Chairman)

Andrew CHENG Kar-foo

Abraham SHEK Lai-him

Starry LEE Wai-king

19 May 2010

Director of Audit's Report No. 53		P.A.C. Report No. 53A
Chapter	**Subject**	**Part**
5	Control of western medicines	4

RULES OF PROCEDURE OF THE LEGISLATIVE COUNCIL OF THE HONG KONG SPECIAL ADMINISTRATIVE REGION

72. Public Accounts Committee

(1) There shall be a standing committee, to be called the Public Accounts Committee, to consider reports of the Director of Audit –

(a) on the accounts of the Government;

(b) on such other accounts required to be laid before the Council as the committee may think fit; and

(c) on any matter incidental to the performance of his duties or the exercise of his powers as the committee may think fit.

(2) The committee shall also consider any report of the Director of Audit laid on the Table of the Council which deals with examinations (value for money audit) carried out by the Director relating to the economy, efficiency and effectiveness of any Government department or public body or any organization to which his functions as Director of Audit extend by virtue of any Ordinance or which receives public moneys by way of subvention.

(3) The committee shall consist of a chairman, deputy chairman and 5 members who shall be Members appointed by the President in accordance with an election procedure determined by the House Committee. *(L.N. 214 of 2005)*

(3A) The chairman and 2 other members shall constitute a quorum of the committee. *(L.N. 214 of 2005)*

(3B) In the event of the temporary absence of the chairman and deputy chairman, the committee may elect a chairman to act during such absence. *(L.N. 214 of 2005)*

(3C) All matters before the committee shall be decided by a majority of the members voting. Neither the chairman nor any other member presiding shall vote, unless the votes of the other members are equally divided, in which case he shall give a casting vote. *(L.N. 214 of 2005)*

(4) A report mentioned in subrules (1) and (2) shall be deemed to have been referred by the Council to the committee when it is laid on the Table of the Council.

(5) Unless the chairman otherwise orders, members of the press and of the public shall be admitted as spectators at meetings of the committee attended by any person invited by the committee under subrule (8).

(6) The committee shall meet at the time and the place determined by the chairman. Written notice of every meeting shall be given to the members and to any person invited to attend a meeting at least 5 clear days before the day of the meeting but shorter notice may be given in any case where the chairman so directs.

(7) *(Repealed L.N. 214 of 2005)*

(8) The chairman or the committee may invite any public officer, or, in the case of a report on the accounts of or relating to a non-government body or organization, any member or employee of that body or organization, to give information or any explanation or to produce any records or documents which the committee may require in the performance of its duties; and the committee may also invite any other person to assist the committee in relation to any such information, explanation, records or documents.

(9) The committee shall make their report upon the report of the Director of Audit on the accounts of the Government within 3 months (or such longer period as may be determined under section 12 of the Audit Ordinance (Cap. 122)) of the date on which the Director's report is laid on the Table of the Council.

(10) The committee shall make their report upon the report of the Director of Audit mentioned in subrule (2) within 3 months (or such longer period as may be determined by the Council) of the date on which the Director's report is laid on the Table of the Council.

(11) Subject to these Rules of Procedure, the practice and procedure of the committee shall be determined by the committee.

Paper presented to the Provisional Legislative Council by the Chairman of the Public Accounts Committee at the meeting on 11 February 1998 on Scope of Government Audit in the Hong Kong Special Administrative Region - 'Value for Money Audits'

SCOPE OF WORK

1. The Director of Audit may carry out examinations into the economy, efficiency and effectiveness with which any bureau, department, agency, other public body, public office, or audited organisation has discharged its functions.

2. The term "audited organisation" shall include -

(i) any person, body corporate or other body whose accounts the Director of Audit is empowered under any Ordinance to audit;

(ii) any organisation which receives more than half its income from public moneys (this should not preclude the Director from carrying out similar examinations in any organisation which receives less than half its income from public moneys by virtue of an agreement made as a condition of subvention); and

(iii) any organisation the accounts and records of which the Director is authorised in writing by the Chief Executive to audit in the public interest under section 15 of the Audit Ordinance (Cap. 122).

3. This definition of scope of work shall not be construed as entitling the Director of Audit to question the merits of the policy objectives of any bureau, department, agency, other public body, public office, or audited organisation in respect of which an examination is being carried out or, subject to the following Guidelines, the methods by which such policy objectives have been sought, but he may question the economy, efficiency and effectiveness of the means used to achieve them.

GUIDELINES

4. The Director of Audit should have great freedom in presenting his reports to the Legislative Council. He may draw attention to any circumstance which comes to his knowledge in the course of audit, and point out its financial implications. Subject to these Guidelines, he will not comment on policy decisions of the Executive Council and the Legislative Council, save from the point of view of their effect on the public purse.

5. In the event that the Director of Audit, during the course of carrying out an examination into the implementation of policy objectives, reasonably believes that at the time policy objectives were set and decisions made there may have been a lack of sufficient, relevant and reliable financial and other data available upon which to set such policy objectives or to make such decisions, and that critical underlying assumptions may not have been made explicit, he may carry out an investigation as to whether that belief is well founded. If it appears to be so, he should bring the matter to the attention of the Legislative Council with a view to further inquiry by the Public Accounts Committee. As such an investigation may involve consideration of the methods by which policy objectives have been sought, the Director should, in his report to the Legislative Council on the matter in question, not make any judgement on the issue, but rather present facts upon which the Public Accounts Committee may make inquiry.

6. The Director of Audit may also -

(i) consider as to whether policy objectives have been determined, and policy decisions taken, with appropriate authority;

(ii) consider whether there are satisfactory arrangements for considering alternative options in the implementation of policy, including the identification, selection and evaluation of such options;

(iii) consider as to whether established policy aims and objectives have been clearly set out; whether subsequent decisions on the implementation of policy are consistent with the approved aims and objectives, and have been taken with proper authority at the appropriate level; and whether the resultant instructions to staff accord with the approved policy aims and decisions and are clearly understood by those concerned;

(iv) consider as to whether there is conflict or potential conflict between different policy aims or objectives, or between the means chosen to implement them;

(v) consider how far, and how effectively, policy aims and objectives have been translated into operational targets and measures of performance and whether the costs of alternative levels of service and other relevant factors have been considered, and are reviewed as costs change; and

(vi) be entitled to exercise the powers given to him under section 9 of the Audit Ordinance (Cap. 122).

PROCEDURES

7. The Director of Audit shall report his findings on value for money audits in the Legislative Council twice each year. The first report shall be submitted to the President of the Legislative Council within seven months of the end of the financial year, or such longer period as the Chief Executive may determine. Within one month, or such longer period as the President may determine, copies shall be laid before the Legislative Council. The second report shall be submitted to the President of the Legislative Council by the 7th of April each year, or such date as the Chief Executive may determine. By the 30th April, or such date as the President may determine, copies shall be laid before the Legislative Council.

8. The Director's report shall be referred to the Public Accounts Committee for consideration when it is laid on the table of the Legislative Council. The Public Accounts Committee shall follow the rules governing the procedures of the Legislative Council in considering the Director's reports.

9. A Government minute commenting on the action Government proposes to take in respect of the Public Accounts Committee's report shall be laid on the table of the Legislative Council within three months of the laying of the report of the Committee to which it relates.

10. In this paper, reference to the Legislative Council shall, during the existence of the Provisional Legislative Council, be construed as the Provisional Legislative Council.

Witnesses who appeared before the Committee
(in order of appearance)

Dr York CHOW Yat-ngok	Secretary for Food and Health
Dr LAM Ping-yan	Director of Health
Mr Anthony CHAN	Chief Pharmacist, Department of Health
Mr Richard YUEN Ming-fai	Commissioner of Customs and Excise
Mr CHEUNG Sai-yan	Head of Trade Controls, Customs and Excise Department
Ms Maria KWAN Sik-ning	Director-General of Trade and Industry
Ms Ellen CHOY	Assistant Director-General of Trade and Industry
Dr LAU Chau-ming	Acting Government Chemist, Government Laboratory
Dr Clare HO	Senior Chemist, Government Laboratory

Introductory Remarks by
Chairman of the Public Accounts Committee,
Dr Hon Philip WONG Yu-hong, GBS,
at the Public Hearing of the Committee
on Tuesday, 8 December 2009

Good afternoon, ladies and gentlemen. Welcome to the Public Accounts Committee's public hearing relating to Report No. 53 of the Director of Audit on the results of value for money audits, which was tabled in the Legislative Council on 25 November 2009.

2. The Public Accounts Committee is a standing committee of the Legislative Council. It plays the role of a watchdog over public expenditure through consideration of the reports of the Director of Audit laid before the Council on the Government's accounts and the results of value for money audits of the Government and those organisations which receive funding from the Government. The consideration by the Committee of the Director's reports involves gathering evidence relevant to the facts contained in the Director's reports, so that the Committee may draw conclusions and make recommendations in a constructive spirit and forward-looking manner. I also wish to stress that the objective of the whole exercise is such that the lessons learned from past experience and our comments on the performance of the public officers or other personnel concerned will enable the Government to improve its control over the expenditure of public funds, with due regard to economy, efficiency and effectiveness.

3. The consideration of the Director's reports follows an established process of public hearings where necessary, internal deliberations and publication of the Committee's report. The Committee has an established procedure for ensuring that the parties concerned have a reasonable opportunity to be heard. After the Committee is satisfied that it has ascertained the relevant facts, it will proceed to form its views on those facts, followed by a process of formulating its conclusions and recommendations to be included in its report. In accordance with Rule 72 of the Rules of Procedure of the Legislative Council, the Committee is required to make its report on the Director's report to the Legislative Council within three months of the date at which the Director's report is laid on the Table of the Council. Before then, we will not, as a committee or individually, be making any public comments.

4. Following a preliminary study of Report No. 53, the Committee has decided, in respect of four chapters in the Report, to invite the relevant public officers and other personnel concerned to appear before the Committee and answer our questions. We have, apart from this afternoon's hearing, also set aside 14, 15 and 17 December 2009 for public hearings on the other chapters.

5. The public hearing this afternoon is on Chapter 7 of Report No. 53 on the subject of "Hong Kong Productivity Council: Corporate governance and administrative issues". The witnesses are: Mrs Rita LAU (Secretary for Commerce and Economic Development), Mr Duncan Pescod (Permanent Secretary for Commerce and Economic Development (Communications and Technology)), Miss Janet WONG (Commissioner for Innovation and Technology), Mr Andrew LAI (Deputy Commissioner for Innovation and Technology), Mr Clement CHEN (Chairman), Mr Wilson FUNG (Executive Director), Mr Tony LAM (Director (Corporate Services)), Mr AU Ming-piu (General Manager (Human Resources and Administration)) and Mr Sam LAW (General Manager (Finance)) of the Hong Kong Productivity Council.

6. Please note that except for designated public officers, other persons are not covered by the protection and immunity provided under the Legislative Council (Powers and Privileges) Ordinance (Cap. 382) when addressing the Committee.

7. I now proceed to the public hearing.

Public Accounts Committee
Public Hearing
Control of Western Medicines
Speaking Notes of the Secretary for Food and Health
on 15 December 2009

Mr. Chairman,

Thank you for inviting me to attend today's hearing.

2. Before the discussion of this Report, let me briefly outline the government policy on the regulation of western medicines.

3. The Government has all along attached great importance to drug safety. Ensuring patient safety and protecting public health is our top priority. For the regulation of drugs, we consider that the following principles should be adhered to:

- Firstly, the regulatory regime should be able to maintain public confidence on the usage of drugs.
- Secondly, the regulatory regime should be able to sustain and improve the standard of the pharmaceutical sector, but at the same time able to identify and address any bad practices.
- Thirdly, the regulatory regime should be fair, consistent and transparent.
- Finally, the regulatory regime has to strike a fine balance between effective regulation and avoidance of unnecessary burden on the trade.

4. Our regulatory regime has been developed on the basis of the above principles. As a matter of course, we also need to take account of the actual situation in Hong Kong in the implementation of drug regulation. For instance, with over 19,000 items of registered drugs and some 1,100 importers, exporters and wholesalers in Hong Kong, there are currently quite a large number of drug items and traders subject to regulation. Under such circumstances, we need to adopt a risk-based approach to drug regulation and target our efforts at more hazardous drugs such as dangerous drugs and poisons.

5. In fact, effective drug regulation requires the co-operation of all parties concerned. We need the collaboration of the trade in combating bad practices. At the same time, we also need the participation of the general public by refusing to buy unregistered drugs and by reporting any bad practices.

6. Earlier this year, the Government set up a Review Committee to conduct a comprehensive review of the existing drug regulatory regime. The review is in its final stage, and the report will be published shortly. The review covers a wide range of issues. Its findings will be conducive to addressing the concerns raised in the Audit Report and setting a clearer direction for the trade to raise their standards so as to ensure patient safety and protect public health. Certainly, we would be pleased to listen to the views of this Committee. With the benefit of inputs from Members, we would be able to do a better job to ensure drug safety.

7. Thank you, Mr. Chairman.

Public Accounts Committee
Public Hearing
Control of Western Medicine
Speaking Notes of the Secretary for Food and Health
on 8 February 2010

Mr. Chairman,

Thank you for inviting me to attend today's hearing.

2. Subsequent to the last hearing, we have published the Report of the Review Committee on Regulation of Pharmaceutical Products in Hong Kong (the Review Report), which contains a total of 75 recommendations. Today, I would like to highlight five issues in the Review Report which are of particular concern to the Public Accounts Committee.

3. Firstly, one of the recommendations put forth in the Review Report is targeted at the diversion of pharmaceutical products imported for re-export purpose into the local market. At present, no registration in Hong Kong is required for certain pharmaceutical products imported into Hong Kong for re-export purpose. To avoid these pharmaceutical products to be diverted into the local market, it is recommended in the Review Report that the control and the tracking of the import and export of these products should be strengthened, including the setting up of a record and tracking system to require export licence applicants to produce the relevant import licences. This will enable staff of the Department of Health to keep track of the amount imported and exported to prevent illegal diversion of drugs imported for re-export purpose into the local market.

4. Secondly, regarding the manufacturing of drugs, the Review Report recommends that the current Hong Kong GMP standard should be upgraded to a higher international standard in 4 years and microbiological monitoring for non-sterile drugs during the manufacturing process should be immediately introduced.

5. Thirdly, the Review Report recommends stepping up the regulation of importers/exporters, wholesalers and retailers, including strengthening the licensing system and introduction of new licensing conditions as well as requiring traders to keep all transaction records and introduction a code of practice, etc. In implementing these recommendations, we will conduct full consultation with members of the trade in an effort to minimise the inconvenience caused to them.

6. Fourthly, the Review Committee also recommends that a new dedicated office on drugs should be set up to strengthen the regulatory role of the Government in enhancing drug safety. The office will formulate plans on drug regulation and direct the implementation of various measures relating to drug safety. In the long run, consideration will be given to expanding the office to become a "Centre for Drug Safety".

7. The Government will take follow-up actions to implement the measures recommended in the Review Report. The Food and Health Bureau will take charge of the policy issues and, together with the Department of Health, study the legislative amendments required and address the resource implications involved. The implementation of some recommendations of the Review Committee requires amendments to the existing Pharmacy and Poisons Ordinance. We will work with the Department of Justice to prepare the legislative amendments. The trade and other stakeholders will be consulted before the legislative proposals are submitted to the Legislative Council.

8. The Government has all along attached great importance to drug safety. Ensuring patient safety and protecting public health is our top priority. We hope that the implementation of the series of recommendations will enhance public confidence on the usage of drugs and maintain a fair, accountable, consistent and transparent regulatory regime. We would be pleased to listen to the views of this Committee. With the benefit of inputs from Members, we would be able to do a better job of ensuring drug safety.

9. Thank you, Mr. Chairman.

Our ref. 本署檔號： DH PS/7-45/14 II
Your ref. 來函檔號： CB(3)/PAC/R53

22 January 2010

Legislative Council
Legislative Council Building
8 Jackson Road, Central
Hong Kong
(Attn: Ms Miranda HON, Clerk
Public Accounts Committee)

Dear Ms HON,

The Director of Audit's Report on the results of value for money audits (Report No. 53)

Control of western medicines (Chapter 5)

I refer to your letter dated 29.12.2009 on the above subject and wish to respond as follows -

(a) the number of convictions related to unregistered medicines and the penalties imposed by the courts in the past three years were as follows -

Year	No. of Convictions	Penalties
2007	39	Fines ranging from $1,000 to $75,000. In one case, a two-month imprisonment suspended for two years was added on

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		top of a $10,000 fine. In another case, a four-month imprisonment suspended for two years was imposed on top of a $10,000 fine.
2008	34	Fines ranging from $1,000 to $20,000. In one case, a four-week imprisonment suspended for two years was imposed instead of a fine. In another case, a two-week imprisonment suspended for one year was imposed on top of a $8,000 fine.
2009	28	Fines ranging from $1,000 to $20,000.

The policy of the Pharmacy and Poisons Board in relation to licensees convicted of offences related to unregistered medicines is at Annex 1;

(b) the Chief Pharmacist has informed me that the proposal of devising a computer system to monitor the import and export of medicines made in 1999 was opposed by small to medium size pharmaceutical importers/exporters. The reason for the opposition was that many companies still did not use computers in their day-to-day operations, and that to mandate the use of computers to submit import and export licence applications would post operational difficulties. Some of these importers/exporters subsequently formed the Pharmaceutical Distributors Association of Hong Kong, which currently has a membership of about 50 small to medium size companies;

(c) the Chief Pharmacist has drawn up a list of suggestions that he had made in the past 10 years for tightening up control of importation of unregistered medicines for re-export purposes. The list is attached at Annex 2.

(d) the numbers of licence applications approved and refused in the past three years were as follows -

	ASPs		LSPs	
Year	No. of Applications Approved	No. of Applications Refused	No. of Applications Approved	No. of Applications Refused
2007	39	0	311	0
2008	35	0	572	1
2009	57	0	337	1

The reason for refusal of the two cases in 2008 and 2009 was that the applicant concerned did not meet the established licensing requirements of any person involved in the ownership or operation of the applicant company having had one conviction related to unregistered medicines, drugs of abuse or counterfeit drugs in the past three years, or two convictions of other drugs in the past three years.

(e) I also attach herewith a copy of the report of the Review Committee.

Yours sincerely,

(Dr P Y LAM)
Director of Health

c.c Secretary for Food and Health (Attn : Ms Shirley LAM) (Fax no. 2526 3753)
Government Chemist (Fax no. 2715 5626)
Secretary for Financial Services and the Treasury
(Attn : Miss Katy FONG) (Fax no. 2147 5239)
Director of Audit (Fax no. 2583 9063)
Secretary for Civil Service (Attn : Ms Jenny CHOI) (Fax no. 2530 5827)

Annex 1

Policy of the Pharmacy and Poisons Board in relation to licensees convicted of offences related to unregistered medicines

Before November 2000 (extracted from minutes of meeting of the Board)

Against authorized sellers of poisons (i.e. ASPs, or dispensaries)

(a) a disciplinary inquiry would be held if an ASP or any of its personnel:

(i) had been convicted of an offence involving the sale of psychotropic drugs or other drugs of abuse or the sale or possession of counterfeit drugs; or

(ii) had had a previous conviction within the last three years;

(b) in all other cases, the proprietor/director and the pharmacist of the ASP would be interviewed by the Chief Pharmacist and the Board's Secretary to give them a verbal caution.

Against listed sellers of poisons (i.e. LSPs, or medicine companies)

(a) an LSP would be removed from the List of LSPs if the LSP or any of its personnel:

(i) had been convicted of an offence involving psychotropic drugs or other drugs of abuse or counterfeit drugs, or a large quantity of controlled drugs; or

(ii) had had a previous conviction within the last three years;

(b) in all other cases, a written warning would be issued to the LSP.

Since November 2000 (extracted from the Licensing and Disciplinary Criteria of the Board)

Against ASPs

A disciplinary inquiry will also be held for first-time convictions involving illegal possession or sale of unregistered medicines. The revised policy is:

(a) a disciplinary inquiry will be held if an ASP or any of its personnel:

- has been convicted of an offence involving psychotropic drugs or sale of cough medicines or zoplicone; or
- has been convicted of illegal possession or sale of unregistered pharmaceutical products; or
- has been convicted of illegal possession for sale or for any purpose of trade or manufacture goods to which a forged trademark is applied; or
- had a previous conviction, the date of offence of which had been within three years of the date of offence of the present conviction.

(b) For other infringement, the proprietor/director and pharmacist of the ASP will be interviewed by the Chief Pharmacist and the Board's Secretary to give them verbal caution in all other cases.

Against LSPs

An LSP will also be removed from the List of LSPs for first-time convictions involving illegal possession or sale of unregistered medicines. The revised policy is:

(a) an LSP will be removed from the List of LSPs if the LSP or any of its personnel:

- has been convicted of an offence involving psychotropic drugs or other drugs of abuse; unregistered pharmaceutical products; or a large quantity of controlled drugs; or
- has been convicted of possession for sale or for any purpose of trade or manufacture goods to which a forged trademark is applied; or
- had a previous conviction within the last three years, the date of offence of which had been within three years of the date of offence of the latter conviction.

(b) in all other cases, a written warning will be issued to the LSP.

Annex 2

Statement by Chief Pharmacist, Department of Health in response to the letter from Clerk to Public Accounts Committee dated 29.12.2009

I would first apprise the Public Accounts Committee of the overall environment on Government Expenditure in 1999-2007 as follows –

1. Under an Enhanced Productivity Programme (EPP), government departments were required to reduce, between April 1999 and March 2003, their baseline expenditure by a total of 5%.

2. A Voluntary Retirement Scheme was launched in July 2000.

3. Against a forecast of huge fiscal deficit, the then Financial Secretary announced in February 2003 a target to reduce operating expenditure by $20 billion from 2003-04, to $200 billion by 2006-07 through, inter alia, the following measures :

   - ✓ reducing civil service establishment by 10%
   - ✓ launching a second round of Voluntary Retirement Scheme
   - ✓ freezing civil service recruitment.

4. The civil service recruitment freeze introduced in April 2003 was lifted in April 2007.

5. There were no Resource Allocation Exercises (RAEs) in 1999-2004, except for 2001. The 2000 RAE was restricted to major policy initiatives.

The following suggestions which I made in the past 10 years for tightening up control of importation of unregistered medicines for re-export purposes should be seen against the above background –

1. seeking the agreement of the Department not to reduce the number of staff involved in inspection and prosecution duties when the Government implemented the EPP in 1999-2003. Proposal accepted by Department;

2. excluding the Pharmacist grade, which forms the backbone for undertaking inspection and prosecution duties, from the two rounds of Voluntary Retirement Schemes in 2000 and 2003. Proposal accepted by Department;

3. tightening post-conviction actions against licensed retailers by the Pharmacy and Poisons Board in respect of convictions involving unregistered medicines: instead of a warning, a disciplinary enquiry to be held against convicted authorized sellers of poisons (ASPs), and licence removal against convicted listed sellers of poisons (LSPs). Proposal implemented in November 2000. As a result of this, from 2001 to 2009, 49 ASPs were convicted, in which 22 had suspension of licence, and 50 LSPs were convicted, in which 27 had their licence removed;

4. amending legislation to require importers to keep full transaction records of unregistered medicines imported for the purpose of re-export, to submit copies of the same to the Pharmacy and Poisons Board as and when required, and to make them available for inspection on site as and when required. Proposal agreed by the Pharmacy and Poisons Board and submitted to the then Health, Welfare and Food Bureau in February 2001. (It subsequently transpired that, as per legal advice received from the Department of Justice, amendment of the principal ordinance would be required in addition to amendment of the subsidiary legislation);

5. making submissions to strengthen manpower provision to enhance the control of medicines. Without divulging the details of RAEs, which is an internal process, the manpower provision of the Department of Health (including those for the control of medicines) is set out in the Annual Estimates of the Government.

(A.W.K. Chan)
Chief Pharmacist
Department of Health
22.1.2010

Report of the

Review Committee on
Regulation of Pharmaceutical Products in Hong Kong

Food and Health Bureau

December 2009

CONTENT

*Note by Clerk, PAC: ***Chapters 1 to 10 and Annexes A to J not attached.***

Executive Summary

INTRODUCTION

In early 2009, a number of incidents concerning pharmaceutical products in Hong Kong had caused public concerns on drug safety. The Food and Health Bureau (FHB) and Department of Health (DH) took immediate measures to address the concerns, including the inspection of all local drug manufacturers. As a longer term measure, it was decided that a comprehensive review on the existing regime for the regulation of pharmaceutical products (western medicines) be conducted.

SETTING UP OF THE REVIEW COMMITTEE ON THE REGULATION OF PHARMACEUTICAL PRODUCTS IN HONG KONG

2. The Review Committee on the Regulation of Pharmaceutical Products in Hong Kong (Review Committee) chaired by the Permanent Secretary for Health with members from the pharmaceutical sector, medical profession, academia, patient groups and consumer representative was set up on 24 March 2009. In consideration of the wide range and complexity of the issues to be examined, the Review Committee set up two Sub Committees, one on drug manufacturing and another on drug distribution and procurement to examine the various issues in depth. A Task Force was also set up under the chairmanship of the Director of Health to provide expert advice to the Review Committee, and an Expert Group was set up to give advice on the microbiological hazards on drug manufacturing. The background of the review, the terms of reference, membership and work of the Review Committee, the two Sub Committees, the Task Force and the Expert Group are set out in Chapter 1 (and Annexes A to C) of this report.

PRESENT SITUATION

3. The current drug regulatory regime adopts a risk management, dual target and multi-pronged approach backed by the law. The dual targets are the pharmaceutical products and the pharmaceutical trade. Multi-pronged approach embraces legal requirements and administrative measures which provide the framework of the control system, education for the pharmaceutical sector to equip them with the necessary professional knowledge, promotion and publicity to remind the public of the importance of drug safety, and a penalty system to deter the pharmaceutical sector from malpractices. The control system starts at

the source of supply of drugs and follow through each point in the production line and the supply chain until the drug reaches its target patients. The framework of the regime is similar to those of many overseas jurisdictions, but the implementation details could differ from one place to another. Chapter 2 of the review report provides an overview of the existing regulatory regime.

UNDERLYING PRINCIPLES OF THE REGULATORY REGIME

4. The Review Committee agrees that the regulatory regime of the pharmaceutical sector should adhere to the following key principles and objectives:

(a) protecting public health and ensuring patient safety is the top priority;

(b) the regulatory regime should be able to maintain public confidence on the usage of drugs;

(c) the regulatory regime should be able to sustain and improve the standard of the pharmaceutical sector, but at the same time able to identify and address any bad practices;

(d) the regulatory regime should be fair, accountable, consistent and transparent; and

(e) the regulatory regime has to strike a fine balance between effective regulation and the challenges to the trade and the professionals.

5. The Review Committee agrees that while the Government has the responsibility to regulate, the pharmaceutical trade has the responsibility to comply with the prescribed requirements and standards, to enhance governance and the audit process. The pharmacist profession and all healthcare professionals have the responsibility to discharge their duties and uphold their high professional standards.

FINDINGS AND RECOMMENDATIONS OF THE REVIEW

6. With the above principles in mind, the Review Committee has examined in detail the existing regulatory regime. It considers that the framework and the rationale behind the existing regime is sound and while it should continue to be adopted, the coverage and depth of the regulatory

measures should be enhanced. The Review Committee is, however, mindful of the implementation details and considers that while changes should be made to enhance the effectiveness of the regime, various proposed new measures should have an implementation programme, taking into account the lead time required to acquire resources, train the personnel both within DH and in the trade, set up the system for the stakeholders to follow or adapt, and to take forward the legislative amendments. Nevertheless, proposals which are key to enhance drug safety should be implemented with priority. At the same time, the Review Committee believes that the pharmaceutical sector plays a pivotal role in protecting the integrity of the system by observing self-discipline and upholding the pharmacist professional standards.

7. The Review Committee has made a total of 75 recommendations, covering the following different aspects as summarised in the ensuing paragraphs (and Annexes D and E).

(a) Regulation of drug manufacturers and Good Manufacturing Practices (GMP) Scheme (Chapter 3)

(i) **To upgrade the current Hong Kong GMP standard to a higher international standard**: GMP is a quality assurance approach used by the drug manufacturing industry worldwide to ensure that products are consistently produced and controlled throughout the manufacturing process. The spirit of GMP emphasizes that the assessment of good quality should be based on scrutiny of the manufacturing processes and not by testing of the end product alone. Hong Kong is now adopting the GMP standard promulgated by the World Health Organization (WHO) in 1995. The Review Committee recommends that in about two years' time the GMP standard of Hong Kong be first upgraded to the standard promulgated by WHO in 2007, and in about another two years' time it should be upgraded to an even higher standard devised by the Pharmaceutical Inspection Cooperation Scheme, i.e. the PIC/S standard. The PIC/S standard includes a stricter control over the use of active pharmaceutical ingredients for drug manufacturing, more stringent qualification requirements for the position of the authorized person who oversees the entire drug manufacturing process, a more enhanced inspection and licensing arrangement, and a more comprehensive training framework for all levels of personnel involved in the GMP system. This recommendation should be implemented with priority.

(ii) **To introduce microbiological monitoring for non-sterile drugs during the manufacturing process**: In the light of the earlier incident of fungal contamination of drugs, the Review Committee recommends that local manufacturers be required to conduct microbiological tests for non sterile drugs. Drug manufacturers will be required to adopt a new model for microbiological monitoring, including the carrying out of microbiological tests on raw materials, limiting the time whereby the granules can be kept to not more than 48 hours, conducting microbiological tests on finished products and including microbiological testing in the stability studies of all products. If a manufacturer intends to adopt a longer holding time, he must provide the necessary data and evidence supporting the proposed holding time to DH for consideration. This recommendation should be implemented with priority.

(iii) **To tighten up the qualification of the Authorized Person (AP) by increasing the required number of years of industrial experience and imposing requirements on training**: A formal set of criteria regarding the qualifications of the AP will be set, alongside with the introduction of a structured training programme and a mechanism to ensure that APs will take responsibility for the quality, safety and efficacy of their drug products. In the meantime, the position of AP will still be required to be filled by pharmacist with relevant experience. In the long run when a licensing or listing system for APs and additional formal certified GMP training have been developed, consideration will be given to allowing additionally non-pharmacists with the required experience and training to assume the position of AP.

(iv) **To require 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. This recommendation should be implemented with priority.

(b) Pre-market control of drugs (Chapter 4)

(i) **To require bioavailability and bioequivalence (BABE) studies for drug registration**: BABE refers to the therapeutic equivalence of the same pharmaceutical product manufactured by different manufacturers. BABE studies seek to assess whether a generic

drug produces the same therapeutic effect as the patent drug. This is particularly important for some drugs, such as antiepileptic drugs, where a reduced or excessive therapeutic effect could be harmful to the patient. The Review Committee recommends that BABE studies be required for drug registration. To allow time for the market to build up its capacity for carrying out the studies, the recommendation will be implemented in phases, starting with drugs where a reduced or excessive therapeutic effect could have undesirable consequences.

(ii) **To Change 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 that alternative terms be devised. One recommendation is to adopt the terms "prescription drugs 處方藥" and "drugs under supervised sale 監售藥". The Pharmacy and Poisons Board should consult the stakeholders on the most appropriate terms.

(iii) **DH to shorten the processing time for drug registration approval**: As a result of manpower constraints, the processing time for approval of registration of drugs, for change of particulars of registered drugs and for clinical trials are quite long. The Review Committee recommends that DH shortens the time by 40% - 50%.

(c) Regulation of importers/exporters, wholesalers and retailers (Chapter 5)

(i) **To require 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 DH requires all wholesalers of non-poisons to apply for a licence so that DH could impose licensing requirements on them.

(ii) **To require 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. This will ensure that drugs are being

procured through a proper channel and the sources can be traced if problems arise.

(iii) **To introduce a Code of Practice for wholesalers, importers and exporters**: At present there are no guidelines governing the roles and responsibilities of wholesalers, importers and exporters on product quality, as opposed to the GMP compliance for manufacturers. The Review Committee recommends that a Code of Practice be introduced for wholesalers, importers and exporters to follow.

(iv) **To strengthen the control of the import and export of pharmaceutical products:** The Review Committee recommends DH to deploy a designated team to provide advice to the Customs and Excise Department (C&ED) at ports of entry and to undertake surveillance work.

(v) **To strengthen the tracking system for drugs imported for re-export purpose:** The Review Committee recommends DH to set up a record and tracking system so that export licence applicants are required to produce the relevant import licences of the imported drugs to be re-exported. This will enable DH staff to keep track of the amount imported and the amount intended to be exported to prevent illegal diversion of drugs imported for re-export purpose into the local market. In the long run, an electronic record system which is inter-operable with C&ED and the Trade and Industry Department should be a more efficient alternative. In addition, the weekly quota of post-shipment consignment checks of licence by C&ED will be increased, taking into account the workload of C&ED staff.

(vi) **To require 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.

(vii) **To require the presence of pharmacists during all business hours of pharmacies**: At present, a registered pharmacist has to be present in an Authorized Sellers of Poisons (ASPs), i.e. pharmacies, for not less than two-third of its opening hours. The Review Committee recommends that in the long run a registered

pharmacist should be present whenever an ASP is open for business. This will improve the professional services provided by pharmacists. To further enhance the role of pharmacists in the control of the storage and supply of drugs at ASPs, apart from the above proposal, heightened enforcement actions should be taken against non-pharmacists who have violated the law or interfered with the duties of pharmacists. The Review Committee noted that this recommendation should take into account the market operating conditions as well as the availability of sufficient pharmacists and cannot be implemented immediately.

(viii) **To include in the law the requirement for retailers to follow their Codes of Practice**: The existing Code of Practice for ASPs, i.e. pharmacies, has no legal status for enforcement, and there is no Code of Practice for Listed Seller of Poisons (LSPs), i.e. medicine companies, to follow with regard to the handling of drugs. The Review Committee recommends that a Code of Practice be devised for LSPs and the law be amended to require that both ASPs and LSPs have to follow their respective Codes of Practice.

(ix) **To empower 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 an ASP can be revoked if it has committed a serious offence.

(x) **To require retailers and doctors to have written records for drug orders**: This is to ensure that there is proper record and checking mechanism to prevent errors during delivery of drugs which is necessary to protect the safety of patients. The Review Committee notes that the trade would need time to work out a system with the suppliers. In the long run, electronic record should be a more efficient alternative. The Review Committee also notes that the written record requirement is already recommended in the "Good Dispensing Practice Manual" issued by the Hong Kong Medical Association and the Hong Kong Medical Council has advised doctors to observe the Manual. The Hong Kong Doctors Union objects to the mandatory requirement of written order of drugs.

(d) Procurement and supply of pharmaceutical products in the public and private medical sectors (Chapter 6)

(i) **The Hospital Authority (HA) and DH to require suppliers to provide detailed information on the delivery documentation:** HA and DH will require supplier to provide information such as pack size and registration number in the delivery documents to enable more effective checking and verification of drugs received. This recommendation should be implemented with priority.

(ii) **HA and DH to check the quality of drugs**: Microbiological and chemical testings will be conducted to ensure drug quality. This recommendation should be implemented with priority.

(iii) **DH to encourage the private medical sector to follow the proposed set of guiding principles on drug handling**: DH will issue a set of guiding principles for all private hospitals. The principles include the selection, procurement, delivery and receipt, storage and repacking of drugs, staff training and auditing. This recommendation should be implemented with priority.

(e) Post-market control of drugs and Pharmacovigilance (Chapter 7)

(i) **DH to continue the extended coverage for the surveillance of high risk products in the market**: DH has increased the number of drug samples collected in the market for testing to over 2 000 in recent years. The Review Committee recommends DH to continue with such rigorous surveillance and the existing practice of reporting anomalies to the public. This recommendation should be implemented with priority.

(ii) **DH to enhance Pharmacovigilance activities**: Pharmacovigilance is the detection, assessment, understanding and prevention of adverse effects of drugs. DH will promote these activities through education, training and promotion among healthcare professionals and the trade and to foster a culture of awareness of pharmacovigilance.

(f) Risk communication, education and training (Chapter 8)

(i) **DH to set up a dedicated team for education and training**: At present there is no coordination amongst various organizations which provide public education programmes on drug safety. The

Review Committee recommends DH to set up a dedicated team to coordinate the efforts of various parties, to draw up guidelines on risk communication and to perform risk assessment in response to incidents and to recommend risk communication actions. This recommendation should be implemented with priority.

(ii) **DH to provide more information on drugs to the public**: Drug information in the existing DH's electronic compendium of pharmaceutical products are not comprehensive and user friendly enough. The Review Committee recommends that the content of the compendium be enhanced. The Review Committee also recommends the setting up of a designated website to promote drug safety. This recommendation should be implemented with priority.

(g) Penalty review (Chapter 9)

(i) **To strengthen the penalty on manufacturers**: The Review Committee recommends authorizing the Manufacturing Licensing Committee of the Pharmacy and Poisons Board to remove the authorized person when he breaches his duties and to stop the production of the manufacturer when the authorized person has been removed.

(ii) **To require 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.

(iii) **To provide the Court with more background information in prosecution cases:** DH should present more information to the Court to reflect the seriousness of the offence concerned for the Court to consider the penalty proportionate to the seriousness of the offence.

8. Chapter 10 of this report provides a general assessment on the resources implications of implementing the recommendations, while Chapter 11 summarizes the recommendations and concludes the work of the Review Committee. A glossary of terms is at *Annex F* for reference.

WAY FORWARD

9. The Review Committee has completed its task by giving recommendations on the measures to improve the existing regime. The Government will take follow up actions to implement these measures. The Food and Health Bureau will oversee the policy issues, and together with the Department of Health, will take forward the necessary legislative amendments, address the resource implications and requirements involved. The Department of Health and Hospital Authority will also be responsible for the implementation of the recommendations, consulting the stakeholders in the process. The implementation programme of the various recommendations is set out at *Annex D*. Some of the recommendations will be implemented subject to the passing of the relevant legislative amendments and may require a longer timeframe for implementation. A list of such recommendations is at *Annex E*.

10. Whilst the recommendations will be implemented in different phases, the Review Committee also recommends that a dedicated office on drugs should be set up to strengthen the regulatory role of the Government in enhancing drug safety in Hong Kong as a matter of priority . The office will plan and direct the implementation of measures relating to drug safety. DH will work closely with the pharmaceutical trade and all stakeholders to plan for the setting up of the office. In the long run, consideration will be given to expanding the office to be a "Centre for Drug Safety".

11. The Review Committee also notes that the Pharmacy and the Poisons Ordinance needs to be kept under regular review taking into account the changes in the operating environment of the pharmaceutical trade.

12. The Review Committee Chairman expresses her gratitude to all its Members, the pharmaceutical and medical sectors, academia, patient groups and consumer representative for their invaluable advice and unfailing support during the whole course of the review. The recommendations of the Review Committee will be implemented through the tripartite collaboration among the regulatory authority, the trade and consumers. All parties would need to maintain their heightened vigilance against any mal-practices. We believe that the key to the success in raising the standard of the pharmaceutical sector in Hong Kong lies in an effective regulatory regime, the commitment and determination of the professionals to practise to their highest standards and the trade to perform responsibly.

IN MEMORIAM

13. The Review Committee is very saddened that one of its Members, Ms Sandra CHOW, Chairperson of Care for your Health - Cardiac Patients Mutual Support Association, passed away in late-December 2009 just before the completion of this review. Ms CHOW had participated actively in all meetings of the Review Committee as well as its subcommittees and had contributed many useful and constructive ideas from the patients' perspective on a wide range of topics. The Chairman and all Members of the Review Committee would like to express their deepest condolences to Ms CHOW's family.

CHAPTER 11 SUMMARY OF RECOMMENDATIONS

Overview

11.1 This chapter gives a summary on all the recommendations and concludes the work of the Review Committee.

Summary of Recommendations

11.2 The Review Committee has made a total of 75 recommendations as follows. Recommendations which can be implemented with existing resources are marked with an "*" while recommendations which will be implemented when new resources are available are marked with an "#".

Regulation of Drug Manufacturers

Recommendation 1# – to upgrade Hong Kong's current GMP licensing standards by a phased approach to PIC/S standards over a period of fours years. (paragraphs 3.15 – 3.16 above)

Recommendation 2# – to require imported drugs to comply with the same standards once local drugs attained the PIC/S standards. (paragraph 3.17 above)

Recommendation 3# – to strengthen the control of the use of Active Pharmaceutical Ingredients (APIs) and contract laboratories by local manufacturers. (paragraph 3.18 above)

Recommendation 4* – to strengthen the experience requirement for existing APs from at least one year of relevant working experience to at least three years; and for the heads of production and quality control from at least one year to at least two years for pharmacy degree holders and from at least two years to at least three years for holders of higher diploma in pharmacy-related subjects. (paragraph 3.19 above)

Recommendation 5# – to draw up a set of qualification requirements of Authorized Persons (APs), to establish a licensing or listing scheme and to liaise with the universities for offering a structured training programme for APs. (paragraph 3.20 above)

Recommendation 6# – to empower the Pharmacy and Poisons Board to maintain an AP register and remove any AP from the register should he be found incompetent to perform the AP role. (paragraph 3.22 above)

Recommendation 7* – to increase the number of inspections to local manufacturers. While most of the inspections to manufacturing premises should remain announced, some unannounced inspections should be introduced. Further, one of the two inspectors in the inspection team should be retained for subsequent inspections to facilitate effective follow-up on irregularities identified. (paragraph 3.25 above)

Recommendation 8# – to set up a multi-disciplinary GMP inspection team with professionals of other related disciplines like biochemists, chemists, engineers, microbiologists, etc. for effective auditing of manufacturers with diversified production environment. (paragraph 3.27 above)

Recommendation 9# – to develop structured, practical and continuous training programmes for all levels of players in the GMP system including DH inspectors, APs, production and quality control heads, and other workers. (paragraph 3.28 above)

Recommendation 10* – to state in the licensing conditions that local manufacturers should either (a) appoint the AP as a board member; or (b) invite the AP to attend board meetings and allow the AP to speak and have his remarks put on record where safety, efficacy and quality issues of products are concerned. This recommendation should be put on trial for two years and then reviewed. (paragraphs 3.29 – 3.32 above)

Recommendation 11# – to introduce a code of practice to govern the conducts of the manufacturers and the APs. (paragraph 3.33 above)

Recommendation 12* – to require all local manufacturers to adopt the enhanced microbiological monitoring model covering raw materials, granules, finished products and stability studies. (paragraphs 3.34 – 3.39 above)

Pre-market Control of Drugs

Recommendation 13# – to require BABE studies as registration requirement for pharmaceutical products to enhance quality of generic drugs. The implementation should be by phases starting in April 2010. It will begin with antiepileptic drugs, which have a narrow therapeutic index where a comparatively small difference in the absorption of the drug by the human body may lead to undesirable consequences. (paragraph 4.14 above)

Recommendation 14* – to replace the term "Poison 毒藥", as required to be labelled on pharmaceutical products classified as poisons, with other terms to alleviate the unnecessary concern of consumers that the products might be harmful and unsuitable for use or consumption. (paragraph 4.15 above)

Recommendation 15* – to delete the phrase "to be marketed for use within Hong Kong" on the certificate of registration of pharmaceutical products. (paragraph 4.16 above)

Recommendation 16* – to extend the validity of clinical trial certificate from not more than two years to not more than five years. (paragraph 4.17 above)

Recommendation 17# – to shorten the time-frame for processing applications for registration of pharmaceutical products, change of particulars of registered products and clinical trials by 40% - 50%. (paragraph 4.18 above)

Regulation of Importers/Exporters and Wholesalers

Recommendation 18# – to require all wholesalers of non-poisons to be subject to inspection and licensing control. (paragraphs 5.17 – 5.18 above)

Recommendation 19# – to require all wholesalers to keep transactions records of all pharmaceutical products, including Part II poisons and non-poisons in the same manner as for Part I poisons, and to require wholesalers to keep samples of each batch of drugs handled to facilitate investigation when needed. (paragraphs 5.19 – 5.20 above)

Recommendation 20* – to require both primary and secondary packaging be carried out by a licensed manufacturer. (paragraphs 5.21 – 5.22 above)

Recommendation 21* – to introduce a code of practice for importers/exporters and wholesalers detailing their roles and responsibilities, including the requirement of batch release certificate, the reporting of adverse drug reactions, proper storage and transportation of drugs, etc. (paragraphs 5.23 – 5.24 above)

Recommendation 22# – to strengthen the monitoring of importers/exporters and wholesalers by means of more frequent and more detailed inspections, especially after the introduction of a code of practice. (paragraphs 5.25 – 5.26 above)

Recommendation 23# – to set up a dedicated team of pharmacist inspectors to advise C&ED staff on pharmaceutical imports at various ports of entry. (paragraphs 5.27 – 5.28 above)

Recommendation 24# – to set up a record and tracking system by requiring EL applicants to produce the ILs of the imported drugs to be re-exported. (paragraph 5.29 above)

Recommendation 25# – to prescribe in the licensing conditions for ILs for the products for re-export that the importer should not sell unregistered imported drugs in Hong Kong and must re-export the products within a specified period of time, say one year. (paragraph 5.30 above)

Recommendation 26# – to conduct a joint review with C&ED to determine a new weekly quota for post-shipment consignment checks of licences which should be a statistically significant sample size of the ILs and ELs population. (paragraph 5.31 above)

Recommendation 27# – to require exporters who chose to export products by mail to clear their products at designated post offices. DH should include the requirement in the ELs and discuss with C&ED for the introduction of a daily quota on outgoing mail parcels of drugs for verification of content and endorsement by C&ED. (paragraph 5.32 above)

Recommendation 28# – to develop an electronic record system among DH, C&ED and TID to facilitate the tracking of imported and exported drugs. (paragraph 5.33 above)

Regulation of Retailers

Recommendation 29# – to require all retailers of non-poisons to be subject to licensing and inspection control. (paragraphs 5.49 – 5.50 above)

Recommendation 30# – in the longer term after taking into account the market operating conditions and the availability of sufficient pharmacists, to require the presence of a registered pharmacist whenever an ASP is open for business. Heightened enforcement actions should be taken against those non-pharmacists who violate and interrupt the pharmacists' performance of their duties at ASPs. (paragraphs 5.51 – 5.54 above)

Recommendation 31* – to require all Part I Poisons be stored in locked receptacle in the premises of an ASP and that only the pharmacist should hold the key to the locked receptacle. (paragraphs 5.55 – 5.56 above)

Recommendation 32* – to add a provision in the Pharmacy and Poisons Ordinance for the issuance and revision of the code of practice for ASPs in order to give a legal status to the code to enhance monitoring on the operation of ASPs; and to introduce a code of practice for LSPs which should enjoy the same legal status as the code for ASPs. (paragraphs 5.57 – 5.58 above)

Recommendation 33* – to give the Pharmacy and Poisons Board the authority to revoke the licence of an ASP at any time after the ASP has been convicted of serious drug offence. (paragraphs 5.59 – 5.60 above)

Recommendation 34* – to tighten the licensing conditions for the refusal or renewal of ASP or LSP applications. DH should evaluate what type of drug offences should be included based on their public health impact. (paragraphs 5.61 – 5.62 above)

Recommendation 35# – to strengthen the monitoring of ASPs and LSPs by means of more frequent and more detailed inspections. (paragraphs 5.63 – 5.64 above)

Recommendation 36* – to require ASPs and LSPs to purchase drugs from licensed traders only. (paragraphs 5.65 – 5.66 above)

Recommendation 37* – to require that all orders for drugs to have written records. (paragraphs 5.67 – 5.73 above)

Recommendation 38* – to require ASPs to sell pharmaceutical products in their original packing, save in the case of a doctor prescription drug which is required by law to be dispensed in exact quantity in accordance with the prescription and in the case of pharmacist dispensing drugs to patients according to their need with proper labelling. (paragraphs 5.74 – 5.75 above)

Recommendation 39* – to require ASPs and LSPs to keep all the supporting documents including drug orders and sales invoices related to every purchase of all pharmaceutical products, and the documents should be kept as long as the expiry date of the pharmaceutical product concerned for DH's inspection if necessary. (paragraphs 5.76 – 5.77 above)

Regulation of Drug Procurement

Recommendation 40# – both DH and HA to conduct post-delivery surveillance including microbiological and chemical testing to ensure drug quality. (paragraph 6.14(a) above)

Recommendation 41* – both DH and HA to require the suppliers to provide additional information, such as pack size and registration number, etc. in the delivery documents to enable more effective physical checking and verification if drugs received are legally conforming. (paragraph 6.14(b) above)

Recommendation 42# – both DH and HA to provide additional training to staff and monitor the workflow in the repacking activities in drug dispensing to minimize errors. (paragraph 6.14(c) above)

Recommendation 43* – to impose a new requirement on suppliers to keep samples of each batch of drugs that are still within the expiration period to facilitate investigation when needed. (paragraph 6.14(d) above)

Recommendation 44# – to upgrade DH's central inventory monitoring computer system to enhance the traceability of drugs. (paragraph 6.14(e) above)

Recommendation 45# – DH to enrich the database of registered pharmaceutical products so as to provide more detailed information to the public on registration details of products, e.g. pack-size, labelling, legal classification, etc. (paragraph 6.14(f) above)

Recommendation 46* – HA to require suppliers to provide evidence that their products are either registered or are exempted from registration under the law. (paragraph 6.14(g) above)

Recommendation 47* – HA to require suppliers to provide microbiological test results for high risk drug items and batch release certificates on all drugs supplied to HA to ensure safety and quality. (paragraph 6.14(h) above)

Recommendation 48* – HA to use multiple sources for supply of high risk products with high usage volume. (paragraph 6.14(i) above)

Recommendation 49# – HA to establish a Drug Quality Assurance Office to enhance quality monitoring of products, performance management of manufacturers and suppliers and quality incident management as well as to monitor the implementation of all improvement initiatives. (paragraph 6.14(j) above)

Recommendation 50# – HA to enhance the current electronic system, such as exploring the use of RFID, bar coding, wireless data transmission, etc. to enable product traceability and effective stores management. (paragraph 6.14(k) above)

Recommendation 51* – HA to require suppliers to provide drugs in suitable pack sizes as far as possible to reduce the need for repacking. (paragraph 6.14(l) above)

Recommendation 52* – DH to issue a set of guiding principles on drug procurement for the private medical sector and encourage private hospitals, MCOs and private medical practitioners in solo or joint practices to follow this set of guiding principles as far as practicable. (paragraphs 6.26 – 6.27 above)

Recommendation 53* – DH to encourage private hospitals to develop an automated inventory management system and bar-coding system for pharmaceutical products. (paragraphs 6.28 – 6.29 above)

Pharmacovigilance

Recommendation 54* – to establish a pharmacovigilance advisory body to review DH assessments of the ADR reports received, advise DH on action on specific cases, serve as an editorial advisory board of the pharmacovigilance bulletin and assist DH in the promotion of pharmacovigilance activities. (paragraph 7.16 above)

Recommendation 55# – DH to set up a dedicated team to promote pharmacovigilance work among professionals, education institutions and the industry; handle ADR reports received; disseminate information; and support the pharmacovigilance advisory body. (paragraph 7.17 above)

Recommendation 56* – DH to publish a regular pharmacovigilance bulletin for distribution to all doctors, dentists and pharmacists, and a user-friendly version of the bulletin for reference of the general public. (paragraph 7.18 above)

Recommendation 57# – DH to include an ADR report form in mails to doctors and pharmacists, enhance DH website such that doctors and pharmacists could subscribe and receive emails from DH on ADR as soon as they become known, encourage the use of electronic reporting of ADRs, and develop additional electronic interface for dentists and pharmacists to facilitate ADR reporting. (paragraph 7.19 above)

Recommendation 58# – DH to publish guidelines for the drug industry on their responsibilities to report ADRs, to educate and encourage them to report ADRs and to develop a culture of awareness of pharmacovigilance. (paragraph 7.20 above)

Recommendation 59* – to require the drug industry to report any actions taken by overseas drug regulatory authorities on any drugs as a consequence of safety issues and require manufacturers to inform DH if they have committed to the request of European Union or United States to develop an EU Risk Management Plans (RMP) or US Risk Evaluation and Mitigation Strategies (REM) as a condition for approving a new drug. (paragraph 7.21 above)

Recommendation 60* – DH to review ADR reports within three working days. (paragraph 7.22 above)

Recommendation 61* – DH to establish liaison with overseas health authorities for exchange of ADR information as well as providing training on pharmacovigilance to staff. (paragraph 7.23 above)

Recommendation 62# – DH to review the progress and effectiveness of the development and implementation of the improved pharmacovigilance measures in two years' time. (paragraph 7.24 above)

Recommendation 63# – DH to continue the heightened surveillance against high risk products sold in the market and set up a dedicated team of pharmacists to handle increased sampling of high risk products. (paragraph 7.25 above)

Recommendation 64* – to adopt a risk-based approach in drug recall and public communication. Specifically DH should revise the recall guidelines to include the different stages of recall procedures, the classification of the recall, the level of the recall, the strategy of the recall including the dissemination of information to the public, the responsibilities of the trade including refund, and the monitoring of all follow up actions, including the effectiveness of the recall. (paragraphs 7.26 – 7.27 above)

Recommendation 65* – DH to inform the Consumer Council on every drug recall incident at consumer level to widen the dissemination network of the drug recall message. (paragraph 7.28 above)

Recommendation 66* – DH to add a refund mechanism in the recall guidelines requiring manufacturers and wholesalers to provide refund details to consumers at retail level in the event of drug recall. (paragraphs 7.29 – 7.30 above)

Risk Communication

Recommendation 67# – to set up a dedicated, multi-disciplinary team to oversee education and training. The team should collaborate with and co-ordinate efforts of the academia, Consumer Council and relevant professional

bodies in the provision of education and training programmes on drug safety. (paragraphs 8.12 – 8.13 above)

Recommendation 68# – to continue organizing seminars with additional focus on quality control for the management at different levels of the drug supply chain as well as front-line staff. (paragraphs 8.14 – 8.15 above)

Recommendation 69# – to enhance the content of "Compendium of Pharmaceutical Products" on DH website to provide more information about each registered drug. (paragraphs 8.16 – 8.17 above)

Recommendation 70# – to set up a designated website on drug safety to provide a better platform for information dissemination and exchange. (paragraphs 8.18 – 8.19 above)

Recommendation 71* – to establish a working group to work out the prototype of the enhanced website and its contents. (paragraph 8.19 above)

Recommendation 72# – to require that more information on drugs and patient-oriented advice be provided along with drugs dispensed to patients at hospitals or clinics. (paragraphs 8.20 – 8.21 above)

Penalty System

Recommendation 73* – to include more aggravating factors in the facts of the case submitted to the Court to reflect the seriousness of the offence concerned for the Court to impose an appropriate sentence. (paragraph 9.11(a) above)

Recommendation 74* – to amend the Pharmacy and Poisons Ordinance to include provision for the Court to order the convicted person to pay the analytical costs incurred by the Government to increase the deterrent effect. (paragraph 9.11 (c) above)

Manpower Requirements

Recommendation 75# – to expand DH's Pharmaceutical Service into a dedicated office on drugs to strengthen DH's regulatory role in enhancing drug safety. In the long run, consideration will be given to expanding the office to be a "Centre for Drug Safety". (paragraphs 10.5 – 10.11 above)

Way Forward

11.3 The Review Committee has now completed its task. The Review Committee is pleased that the Government has accepted all its recommendations. In particular, the establishment of a dedicated office on drugs and the raising of Hong Kong's GMP licensing standards to PIC/S standards will become major milestones in the enhancement of Hong Kong's drug safety standard.

11.4 The next step is for the Government to join hands with the pharmaceutical sector in implementing the recommendations. The Food and Health Bureau will oversee the policy issues, introduce the necessary legislative amendments and seek the required resources, while DH, HA and the pharmaceutical sector will be responsible for implementation of the recommendations. The Review Committee would like to appeal to the pharmaceutical sector that it is their primary responsibility to practise to their highest professional standards and strive for continuous service improvement. With the joint efforts of all parties, the Review Committee is confident that the standards of the pharmaceutical industry in Hong Kong will be enhanced and public confidence on the use of drugs will be raised.

11.5 The Chairman of the Review Committee would like to thank all the members of the Committee, the pharmaceutical sector, the medical sector, patient groups and the consumer representative for their contributions to the deliberations of the Review Committee. Members have been most generous with their time and they contributed constructively to all discussions and debates at the meetings in this comprehensive review resulting in a total of 75 recommendations. The Food and Health Bureau and the Department of Health look forward to working with all stakeholders to implement these recommendations under the same spirit of cooperation.

Review Committee on
Regulation of Pharmaceutical Products in Hong Kong
Food and Health Bureau
December 2009

Our ref. 本署檔號： DH PS/7-45/14 II
Your ref. 來函檔號： CB(3)/PAC/R53

11 March 2010

Legislative Council
Legislative Council Building
8 Jackson Road, Central
Hong Kong
(Attn: Ms Miranda HON, Clerk
Public Accounts Committee)

Dear Ms HON,

The Director of Audit's Report on the results of value for money audits (Report No. 53)

Control of western medicines (Chapter 5)

I refer to your letter dated 23.2.2010 on the above subject and wish to respond as follows:

(a) Paragraph 3.46 of the Director of Audit's Report relates to test purchases. DH has reviewed the protocol. Since December 2009, DH has implemented a programme to conduct night-time and weekend test purchases, on top of the usual test-purchases conducted during office hours. Medicines chosen for night-time and weekend test purchases are those likely to be sold at such times, such as sleeping pills and cough medicines. Areas throughout Hong Kong where business hours run late are specially targeted at. In addition, seasonal tactics have also been

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adopted. For example, operations to combat over-the-counter sale of post-coital contraceptive pills were conducted in December 2009 and early January 2010, to coincide with the festive periods of Christmas and New Year. Data are being consolidated for the purpose of reviewing the effectiveness of the new measures.

Besides retail shops, sales on the Internet have also been targeted at. Test purchases for suspected products are conducted, both routinely and as a part of investigations. These test purchases have resulted in a number of public alerts which, among other things, serve to exhort people not to buy or sell products of unknown or doubtful composition.

(b) Each time the registration of a medicine expires and is not renewed, DH issues a notification to the manufacturer or importer concerned, with a specific instruction to recall the medicine. A copy of the notification is attached at Annex for reference. DH also puts the name of the medicine on the inspectors' watch list. During inspections at drug dealers' premises, the inspectors will pay particular attention to ensure that the medicine is no longer available for sale.

(c) Since March 2009, DH has enhanced its monitoring of recalls conducted by manufacturers and importers. For each recall, the company concerned is instructed to submit to DH a detailed distribution list of the product concerned. The distribution list contains the following information:

1. the name of the medicine and batch number to be recalled;
2. the date the batch began to be distributed;
3. the batch size of the medicine;
4. the quantity of the medicine not yet distributed;
5. the name of each institution to whom the medicine has been distributed; and
6. the quantity of the medicine distributed to each

institution and the total quantity distributed.

After the recall is completed, the manufacturer or wholesaler should submit to DH a report listing out the quantity of the medicine recalled from each institution and the total quantity recalled. Officers of DH inspect some of these institutions on a risk-based approach (e.g. those who have obtained a large quantity of the medicine) to check if the medicine has been effectively recalled.

Between March and December 2009, there were ten recalls and about 100 institutions were inspected to follow up on the effectiveness of the recalls. None of the institutions was found to be still in possession of the recalled medicine. This has demonstrated that the enhanced monitoring mechanism is effective.

(d) Paragraphs 5.20 and 5.32(b) of the Audit Report relate to: (i) cancellation of unused and unexpired import and export licences; (ii) removal of all other licences of a multi-licence holder if one of his licences is removed; and (iii) taking into account convictions of related authorised sellers of poisons (ASPs) when assessing applications for ASP registration. DH has consulted the Department of Justice on (iii) above. The advice received will be considered by the Pharmacy and Poisons Board. DH will consult the Department of Justice on (i) and (ii) above shortly.

(e) DH plans to develop a new computer database for registration of medicines in September 2009 in consultation with the Office of the Government Chief Information Officer. This new system is designed to streamline the input of key data of registered medicines such as pack size, quantity of active ingredient, product image, etc. As regards import and export control of medicines, as recommended by the Review Committee on Regulation of Pharmaceutical Products in Hong Kong, DH will set up a record and tracking system for import and export of drugs. DH is also in liaison with the Efficiency Unit to seek their

support and assistance to conduct a feasibility study in developing an integrated IT system among DH, Customs and Excise Department and Trade and Industry Department to enhance the control and to optimise the utilisation of other IT systems within the Pharmaceutical Service of DH.

(f) Immediately after the drug incidents in March 2009, three contract Pharmacists were recruited to enhance the regulatory control of pharmaceutical products. This was followed by ten additional Pharmacists in May 2009, making a total of 13 contract Pharmacists. Subject to the approval of the 2010-11 draft Estimates by the Legislative Council, DH plans to create new posts of 10 Pharmacists and 1 Scientific Officer specialised in microbiology to further strengthen the regulation of pharmaceutical products. Further resources, if required, for implementing the various tasks set out in part (B) of Annex D of the Report will be sought according to the established procedures.

Yours sincerely,

(Dr P Y LAM)
Director of Health

c.c Secretary for Food and Health (Attn : Ms Shirley LAM) (Fax no. 2526 3753)
Secretary for Financial Services and the Treasury (Fax no. 2147 5239)
Director of Audit (Fax no. 2583 9063)

Annex

2319 8453

File:PR ( )

Dear Sirs,

I wish to inform you that the registration of the above-named product(s) will not be renewed because:

- ☐ you have confirmed its non-renewal; or
- ☐ you have failed to provide the required documentation for its renewal.

You should therefore immediately recall the product(s) from the market. Your attention is drawn to the fact that the sale, offer for sale, distribution or possession for the purposes of sale, distribution or other use of unregistered pharmaceutical product(s) is an offence under the Pharmacy and Poisons Regulations.

For enquiries, please contact Judy LAU at **Tel No. 2319 8453**.

Yours faithfully,

(Y.L. MAK)

for Chief Pharmacist

We are committed to providing quality client-oriented service

ASPs	Authorised sellers of poisons
Audit	Audit Commission
Board	Pharmacy and Poisons Board
C&ED	Customs and Excise Department
DDs	Dangerous drugs
DH	Department of Health
DoJ	Department of Justice
ELs	Export licences
EMA	European Medicines Agency
EU	European Union
FHB	Food and Health Bureau
GL	Government Laboratory
GMP	Good Manufacturing Practice
ILs	Import licences
IT	Information technology
LegCo	Legislative Council
LSPs	Listed sellers of poisons
PIs	Pharmacist inspectors
PPO	Pharmacy and Poisons Ordinance (Cap. 138)
WPL	Wholesale poisons licence