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.