Laying of the Report Report No. 53 of the Director of Audit on the results of value for money audits was laid in the Legislative Council on 25 November 2009. The Committee's supplemental report (Report No. 53A) on Chapter 5 of the Director of Audit's Report was tabled on 2 June 2010.

2. **The Government Minute** The Government Minute in response to the Committee's Report No. 53A was laid in the Legislative Council on 20 October 2010. The latest position and the Committee's further comments on these matters are set out in paragraphs 3 and 4 below.

Control of western medicines
(Part 4 of P.A.C. Report No. 53A)

3. The Committee was informed that:

Review of existing regulatory control of medicines

- the Secretary for Food and Health and the Director of Health had accorded priority to ensuring the safety, efficacy and quality of medicines in Hong Kong. In formulating the Government's strategy and preparing legislative amendments to tighten up control, the Food and Health Bureau ("FHB") would take into serious consideration the observations and recommendations of the Audit Commission ("Audit") and the Committee. The FHB also attached great importance to enhancing the regime for the regulation and control of medicines in Hong Kong. The Administration was preparing legislative amendments and finalising the implementation details for improving the regime;

Importation of unregistered medicines

- in order to work closely with other relevant bureaux and departments to tighten up the import and export control of pharmaceutical products, the Department of Health ("DH") had convened a Task Force on Import and Export Control of Pharmaceutical Products with representatives from the FHB, the Commerce and Economic Development Bureau, the Efficiency Unit ("EU"), the Customs and Excise Department ("C&ED"), and the Trade and Industry Department ("TID") to formulate strategies on the control of medicines imported for re-export based on risk assessment and implementation of the recommendations of Audit and

the Review Committee on Regulation of Pharmaceutical Products in Hong Kong. The Task Force was exploring the feasibility of developing a computer system to track the import and re-export of unregistered medicines and the sharing of information among the DH, the C&ED and the TID. The Administration would keep the Legislative Council ("LegCo") Panel on Health Services informed of developments;

Inspection of dealers' activities and other enforcement actions

- in response to the Committee's concern, the DH had taken steps to improve its inspection of dealers' activities and enforcement actions, as well as explore other measures to improve the frequency, quality and effectiveness of inspection and enforcement actions. The DH made unannounced inspections to manufacturers and would uphold the practice as suggested by Audit. The DH planned to enhance the standard of local drug manufacturing in phases and adopt the latest international Good Manufacturing Practices standards, including inspections and reporting. Adopting a risk-based approach, the DH regularly reviewed the frequency and extent of inspection of wholesalers, importers/exporters and authorised and listed sellers of poisons. The DH had also increased the number of test purchases and started to conduct test purchases during weekends and night time. The DH would explore further regulatory measures in collaboration with the Pharmacy and Poisons Board ("PPB") such as requiring authorised and listed sellers of poisons to display their licences at their retail shop entrances and publishing the removal of listed sellers of poisons on the DH's website. The Administration would inform the Committee and the LegCo Panel on Health Services of the progress;

Medicine testing, recalls and public alerts

- the DH accorded a high priority to medicine testing, monitoring of medicine recalls and issuing of public alerts. The DH had enhanced the monitoring system on recalls in response to the recommendations of Audit. It worked closely with the Government Laboratory and had initiated an annual review of the number of test samples and set performance targets for the turnaround time of sample testing based on the risk assessment of medicines selected from the market surveillance system. Outsourcing of certain testing work was being explored;

Licence-refusal criteria, prosecutions and disciplinary actions

- the DH and the PPB had considered the recommendations of Audit on the improvement of the prosecutions and disciplinary actions as well as penalty system, with a view to achieving a greater deterrent effect and protecting the public interest. The DH would actively consider and pursue measures suggested by Audit. The PPB had set up a working group to review and strengthen the licensing criteria. It had revised the registration protocol to include the checking of conviction record of the related authorised sellers of poisons when considering applications for registration. In response to the concern of Audit and the Committee, the PPB had also cleared the backlog of disciplinary cases and imposed heavier penalty for achieving a greater deterrent effect;

Public information and internal support

- the DH was working closely with different stakeholders to enrich information on its website on medicines and dealers, and would ensure that the information was up-to-date. The DH was also conducting a review of the existing information technology systems of its Pharmaceutical Service unit to enhance its regulatory work. Support and assistance from the EU would be sought. The Administration would inform the Committee and the LegCo Panel on Health Services of the progress; and

Progress made in implementing Audit's recommendations

- a summary of progress on implementing Audit's recommendations was set out at in ***Appendix 4***.

4. The Committee wishes to be kept informed of further development on the subject.