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.