中華人民共和國香港特別行政區政府總部食物及衞生局
Food and Health Bureau, Government Secretariat
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

**Our Ref. :** FH/H/LEG/13 (09)

**Tel** : 2973 8293
**Fax** : 2840 0467

3 July 2009

Miss Mary SO
Clerk to Panel on Health Services
Legislative Council
Legislative Council Building
8 Jackson Road
Central, Hong Kong

Dear Miss So,

**Meeting of Legislative Council Panel on Health Services on 31 March 2009**
**Regulation and Control of Pharmaceutical Products in Hong Kong**

At the meeting of the Legislative Council Panel on Health Services on 31 March 2009, we briefed Members on the measures to be taken by the Administration to review and enhance the existing regime for the regulation and control of pharmaceutical products in Hong Kong. Members requested information on the revised checklist used by the inspectors of the Department of Health when conducting inspections on pharmaceutical manufacturers. We hereby provide the relevant information.

**The Review Committee on Regulation of Pharmaceutical Products**

The Review Committee on Regulation of Pharmaceutical Products (Review Committee), chaired by the Permanent Secretary for Food and Health (Health), was set up to undertake a comprehensive review of the existing regulatory regime for the control of pharmaceutical products. The first meeting of the Review Committee was held in April 2009.

To facilitate in-depth examination of the range of issues, the Review Committee formed two subcommittees on drug manufacturing and drug distribution and procurement respectively. A Task Force chaired by the Director of Health was also set up by the Department of Health (DH) to put forward proposals on the updating of the Good Manufacturer Practices (GMP) scheme and on the enhancement of pharmacovigilance. The Task Force has commissioned an overseas expert consultant to conduct relevant study and make reference to the experience of overseas regulatory authorities. It is expected that the work of the Review Committee and the Task Force will be completed by the end of this year.

**Checklist of conducting inspections on pharmaceutical manufacturers**

Currently, DH is in the process of conducting a comprehensive review of the checklist for inspection of local manufacturers. The revised inspection checklist will be available after the completion of the GMP consultancy study on local manufacturers and the subsequent adoption of the consultancy recommendations by the Review Committee. We will provide Members with information on the revised inspection checklist when it is available in due course.

Yours sincerely,

(Ms Shirley LAM)
for Secretary for Food and Health

c.c. Director of Health (Attn : Dr Cindy LAI Fax : 2573 0646
Dr Heston KWONG Fax : 2573 7432)