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

11 March 2010

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

Dear Ms HON,

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

Control of western medicines (Chapter 5)

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

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

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

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

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

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

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

institution and the total quantity distributed.

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

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

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

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

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

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

Yours sincerely,

(Dr P Y LAM)
Director of Health

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

Annex

2319 8453

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Dear Sirs,

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

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

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

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

Yours faithfully,

(Y.L. MAK)

for Chief Pharmacist

We are committed to providing quality client-oriented service