# 立法會
# *Legislative Council*

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**Panel on Health Services**

**Background brief prepared by the Legislative Council Secretariat for the meeting on 11 April 2011**

**The establishment of a dedicated office on drugs**

## Purpose

This paper summarizes the concerns of members of the Panel on Health Services ("the Panel") on issues relating to the establishment of a dedicated office in the Department of Health ("DH") to strengthen DH's capacity in drug regulation.

## Background

2. In Hong Kong, the drug regulatory regime adopts a risk management, dual target and multi-pronged approach underpinned by the Pharmacy and Poisons Ordinance (Cap. 138). The dual targets are the pharmaceutical products and the pharmaceutical trade whereas the multi-pronged approach embraces legal requirements and administrative measures which provide the framework of the control system, education for the pharmaceutical sector to equip the trade with the necessary professional knowledge, promotion and publicity to remind the public of the importance of drug safety, and a penalty system to deter the pharmaceutical sector from malpractices. The control system starts at the source of supply of drugs and follows through each point in the production line and the supply chain until the drug reaches its target patients. The Pharmaceutical Service of DH is responsible for carrying out the drug regulatory functions of DH.

3. In 2009, a number of incidents concerning pharmaceutical products had caused great public concern and called into question public confidence on the adequacy and performance of the existing regime for the regulation and control of pharmaceutical products. These incidents included: a locally-manufactured drug, Allopurinol, was found contaminated by Rhizopus microsporus; 216

pharmaceutical products were being recalled as the label expiry dates of these products were not substantiated by laboratory data; some pharmaceutical products supplied to the Hospital Authority had yet to be registered by DH; suspected unlicensed packaging of pharmaceutical products; and pharmaceutical products supplied to the Hospital Authority not matching with the declaration in label.

4. In the light of the above incidents, the Secretary for Food and Health announced on 19 March 2009 the setting up of a Review Committee on the Regulation of Pharmaceutical Products in Hong Kong ("Review Committee") to conduct a comprehensive review on all the relevant issues including safety and quality assurance of drugs, standard and practices of the pharmaceutical industry, and whether there was a need for legislative amendments. The Review Committee was chaired by the Permanent Secretary for Food and Health (Health) with members from the pharmaceutical sector, medical profession, academia, patient groups and consumer representatives. Apart from forming two respective subcommittees on drug manufacturing and drug distribution and procurement, a Task Force was also set up under the chairmanship of the Director of Health to provide expert advice to the Review Committee, and an Expert Group was formed to give advice on the microbiological hazards on drug manufacturing.

5. The Review Committee published its report in December 2009 with 75 recommendations covering a wide range of areas including: regulation of drug manufacturers, importers/exporters, wholesalers and retailers; pre-market and post-market control of drugs; procurement and supply of pharmaceutical products in the public and private medical sectors; risk communication, education and training; and manpower requirements. In order to implement all the recommendations, the Review Committee proposed the establishment of a dedicated office on drugs to strengthen DH's capacity in drug regulation. The Review Committee also recommended that in the long run, consideration should be given to transforming the dedicated office into a "Centre for Drug Safety".

**Deliberations of the Panel**

Inadequate manpower to ensure drug safety

6. Many members considered that the lack of manpower of DH to perform inspection and surveillance on the drug supply chain was one of the reasons for the series of drug incidents in 2009. To better protect public health, many members urged DH to increase the number of pharmacists in the department. The Administration advised that as an immediate measure, DH would recruit 10

additional pharmacists to strengthen inspection to manufacturers, wholesalers and retailers of drugs and the sampling of drugs for analysis.

7. Noting the huge workload of pharmacists which included: inspection of 25 manufacturers, 240 importers/exporters, 860 wholesalers and 3 800 retailers in Hong Kong; sampling of some 19 500 registered pharmaceutical products for analysis; and conducting investigation on some 600 complaint cases and some 100 drug poisoning incidents annually, some members cast doubt about the extent to which the additional 10 pharmacists could help enhance inspection and surveillance of pharmaceutical products. They urged the Administration to recruit more pharmacists. The Administration advised that DH would consider the need for additional pharmacists in the course of the review on the regulation of pharmaceutical products in Hong Kong.

Establishment of a dedicated office on drugs

8. Some members shared the view of a deputation that it was necessary to have a dedicated office to enhance drug safety, as in the case of the Centre for Food Safety to enhance food safety regulation. They urged the Administration to set up a dedicated office on drugs.

9. While welcoming the recommendation of the Review Committee to transform the Pharmaceutical Service of DH into a dedicated office on drugs to strengthen DH's regulatory role on drug safety, members noted with concern that with the expanded scope of services and responsibilities, the staff strength of the Pharmaceutical Service would be required to increase significantly from around 160 to more than 350. Some members were doubtful whether the additional manpower requirement could be met through programmes offered by local universities.

10. The Administration advised that the Pharmaceutical Service would need to increase staff strength to more than 350 in order to implement all the recommendations of the Review Committee in full. The Administration would liaise with the University Grants Committee with a view to offering more places in the pharmacy programmes of universities, taking into account the supply of pharmacy graduates from overseas.

11. Some members urged the Administration to discuss with the Financial Secretary on the additional money required to hire additional staff in order to expedite the implementation of the recommendations of the Review Committee.

**Latest developments**

12. At the special meeting of the Panel on 15 October 2010 to receive a briefing from the Secretary for Food and Health on the 2010-11 Policy Agenda, members noted that the Administration was working on legislative amendments and implementation details of the recommendations to enhance the regulatory regime for Western medicines.

13. According to the Administration's replies to Members' initial written questions during the examination of estimates of expenditure 2011-12, $27.8 million would be allocated to DH to establish the dedicated drug office to strengthen the existing regulatory activities, including pharmacovigilance; import/export, manufacture, wholesale and retail licensing; inspection; surveillance and complaint investigation. New areas such as risk assessment and risk communication will also be introduced to enhance control on pharmaceutical products for better public health protection. DH would need to create 38 posts, including an Assistant Director of Health, a Chief Pharmacist, two Senior Pharmacists, 14 Pharmacists, five Scientific Officers (Medical) and 15 general grade posts. To meet the increase in demand for pharmacists, the Administration has reviewed and forwarded its manpower requirements to the University Grants Committee in step with the triennial academic development planning cycle.

**Relevant papers**

14. A list of the relevant papers on the Legislative Council website is in **Appendix I**.

Council Business Division 2
Legislative Council Secretariat
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**Appendix I**

**Relevant papers on**
**the establishment of a dedicated office on drugs**

| Committee | Date of meeting | Paper |
|---|---|---|
| Panel on Health Services | 31.3.2009 (Item I) | Agenda<br>Minutes<br>CB(2)2139/08-09(01) |
| Panel on Health Services | 11.1.2010 (Item V) | Agenda<br>Minutes |
| Panel on Health Services | 15.10.2010 | Agenda |
| Finance Committee | 25.3.2011 (Session No.4) | Agenda<br>Administration's replies to Members' initial written questions in examining the Estimates of Expenditure 2011-12 (Reply serial no.: FHB(H)082, FHB(H)130, FHB(H)265 and FHB(H)267) |

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