For information
16 December 2013

Legislative Council Panel on Health Services

Legislative Proposals to Enhance the Regulation of Pharmaceutical Products in Hong Kong

Purpose

This paper reports on the latest developments of the Administration's proposals to enhance the regulation of pharmaceutical products in Hong Kong for Members' reference.

Background

2. At the meeting held on 18 November 2013, the Administration tabled a paper (LC Paper No. CB(2)254/13-14(03)) on the legislative proposals to enhance the regulation of pharmaceutical products in Hong Kong. Moreover, in response to the enquiries on the proposed requirement of written orders of drugs raised by Members at the meeting, the Administration provided supplementary information (LC Paper No. CB(2)414/13-14(01)) at the special meeting held on 10 December 2013 to provide Members with further information on the background, objective and proposed modus operandi of the aforementioned requirement.

3. In the above supplementary information and at the above special meeting, we emphasized once again that, in response to the concern of the trade, the requirement of placing drug orders in written form would be incorporated into the Codes of Practice for the relevant licenced drug traders (including manufacturers, wholesalers and retailers of pharmaceutical products) by the Pharmacy and Poisons Board after consultation with the trade and the relevant stakeholders. Such requirement would become one of the compliance requirements for the relevant licensed drug traders. In other words, the above requirement would not be regulated by the law. As such, our legislative proposals as suggested in the LC Paper No.

CB(2)254/13-14(03) **do not cover** the requirement of written orders of drugs. We are pleased to note that Members and some attending organisations/individuals supported the above arrangement. We trust that as a compliance requirement for the trade, placing drug orders in written form would help enhance the monitoring of the drug supply system and minimise the potential risk in every step of the drug supply chain. This serves to provide the best protection for the public.

4. We are pleased to see that Members and attending organisations/individuals all support the Administration's legislative proposals to enhance the regulation of pharmaceutical products in Hong Kong. Nevertheless, we note that at the above special meeting some Members and organisations expressed reservation to the proposal of requiring registered pharmacist employed by an Authorized Seller Poisons ("ASP") be present whenever the ASP is opened for business, which is longer than the current statutory requirement of two-thirds of the business hours.

Latest Developments

5. As a matter of fact, in formulating the proposal for requiring the presence of registered pharmacist in the registered premises of an ASP whenever the ASP is opened for business, the Administration has already taken into account the current manpower supply of the registered pharmacists. In this regard, we have stated in the LC Paper No. CB(2)254/13-14(03) that the relevant provision for such requirement would be implemented at a later stage. In response to views of some Members and the trade and considering that the manpower supply of registered pharmacists in the coming few years may not be sufficient to cope with the manpower demand arising from the above proposal, coupled with the fact that our original intention is not to implement the above proposal shortly, we consider that there is no imminent need to amend the relevant legislation at this stage. As a result, **the Administration has decided to remove the relevant provision from the legislative proposals**.

Way Forward

6. As stated in the LC Paper No. CB(2)254/13-14(03), the legislative exercise aims to implement some recommendations put forth by the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong ("Review Committee") in response to a number of incidents concerning

pharmaceutical products. By strengthening the regulation of the pharmaceutical products through different aspects and enhancing the management quality of the pharmaceutical sectors, the public can have the best protection.

7. We thank for Members' support to our legislative exercise and their views on our legislative proposals. We are also grateful that the Panel has invited views from the deputations and provided a platform for us to once again exchange views with the trade in relation to the enhancement measures for the regulation of pharmaceutical products in Hong Kong. As indicated in paragraph 5 above, the Administration has decided to adjust its legislative proposals accordingly to address the concerns of some Members and the trade. In order to implement the recommendations put forth by the Review Committee as soon as possible, we plan to introduce the adjusted legislative proposals into the Legislative Council in the first half of 2014.

Food and Health Bureau
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