For supplementary information
on 10 December 2013

Legislative Council Panel on Health Services

The Regulation of Pharmaceutical Products in Hong Kong Supplementary Information on Written Orders of Drugs

Purpose

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. In response to the enquiries on the proposed requirement of written orders of drugs raised by Members at the meeting, this paper serves to provide Members with further information on the background, objective and proposed modus operandi of the aforementioned requirement.

Background and Objective of the Requirement

2. In 2005, a private doctor attributed the serious and fatal consequences caused by inappropriate medications prescribed to 153 patients over a period of five months to the delivery of incorrect drugs by the supplier who had erroneously taken the drug order placed verbally. The private doctor was later found guilty of misconduct by the Hong Kong Medical Council for failing to take adequate steps to verify that the drugs received from the supplier corresponded to the order.

3. We mentioned in the LC Paper No. CB(2)254/13-14(03) that in December 2009 the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong ("the Review Committee") put forth a total of 75 recommendations to enhance the regulation of pharmaceutical products. One of these recommendations is to require that all orders for drugs should have written records. The aim of this requirement is to build up a complete set of drug movement records, thus facilitating the tracing of source of drugs, minimizing errors in the delivery and receipt of drugs and combating illegal sale of drugs.

4. The Administration supports that drugs should be ordered in writing. This is because many drug names are similar and misunderstanding or confusion may easily arise, especially when the orders for drugs are placed verbally. Ordering drugs in written form can effectively reduce the risk of miscommunication. Moreover, there is always a time gap between the ordering and delivery of drugs, and the person who receives the drugs may be different from the one who places the order. Placing orders of drugs in written form would facilitate the staff receiving the drugs to verify the accuracy of the drugs delivered against the information in the written orders. Placing orders of drugs in writing would also ensure smooth and accurate transactions between sellers and buyers.

5. In addition, written orders are normally not used in illegal trading of drugs so as to avoid being traced. In this regard, we believe that the recommendation of the Review Committee, which would enhance existing records in the supply chain of drugs, would facilitate tracing of the source of illegal drugs as well as curbing sale of unregistered drugs and purchase of drugs from unknown traders.

6. Indeed, to avoid recurrence of incident described in paragraph 2 above, the Hong Kong Medical Association ("HKMA") reviewed the Good Dispensing Practice Manual ("GDP Manual") in 2007 and recommended that the ordering of drugs from suppliers should be made in writing and the written orders should be kept for verification upon delivery of the drugs and for future reference. A sample drug ordering form has also been provided in the "GDP Manual" to serve as a reference for practising doctors. As recommended by the HKMA, all practising doctors should comply with the "GDP Manual".

Proposed Modus Operandi

7. We understand the concerns of the industry towards the requirement of written orders of drugs, such as increase in administrative costs and the possibility of delay in the ordering for pharmaceutical products at retail level. However, we consider that the requirement would help enhance the monitoring of the drug supply system and minimise the potential risk in every step of the drug supply chain. All these serve to provide the best protection for the public.

8. Having considered the regulation of the drug supply system and the concerns of the industry, we propose to implement the requirement of placing drug orders in written form by administrative means whereby the Pharmacy and Poisons Board ("PPB") would incorporate the requirement in the Codes of Practice ("COP") for the relevant licenced drug traders (including manufacturers, wholesalers and retailers of pharmaceutical products). The PPB has set up working groups to formulate the COPs for various licenced drug traders. To help the industry adapt to the requirement, the PPB preliminarily considers that placing drug orders by electronic means (e.g. e-mails), fax and mail etc. could be accepted as written orders. In addition, the PPB is considering implementing the requirement of written orders by phases. For instance, in the initial stage of implementation, the requirement would only apply to dangerous drugs, drugs in Part I of the Poisons List of the Poisons list Regulations (Cap. 138B), and antibiotics. The PPB will later consider extending the requirement to drugs with lower risk, such as drugs in Part II of the Poisons List and drugs not included in the Poisons List. The PPB has commenced consultations to collate views from the licenced drug traders, other stakeholders (such as registered pharmacists, doctors, dentists and various associations of the pharmaceutical industry etc.) and consumers. The PPB will take into account views so collated in adjusting / formulating the COPs.

9. As clearly pointed out above, the requirement of written orders of drugs will be implemented through administrative measures, i.e. the requirement will be incorporated into the relevant COPs for which the relevant parties will be required to comply with, instead of regulating by the law. Therefore, 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.

10. Regarding the concerns of the Panel about the impact of the requirement of written orders of drugs on practising doctors, as pointed out in paragraph 6 above, the HKMA has already recommended in its "GDP Manual" that practising doctors should order drugs in writing. Therefore, our requirement is in line with that of the HKMA. We understand that practising doctors have been complying with such requirement since 2007. We therefore believe that this requirement will not impose additional burden on practising doctors.

Food and Health Bureau
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