



中華人民共和國香港特別行政區政府總部食物及衛生局

Food and Health Bureau, Government Secretariat  
The Government of the Hong Kong Special Administrative Region  
The People's Republic of China

**Our Ref.:** FHB/H/19/69 Pt.4  
**Your Ref.:** HKDU/104/2014

**Tel No.:** 3509 8956  
**Fax No.:** 2840 0467

29 October 2014

Dr. Ho Ock Ling  
Hon. Secretary  
Hong Kong Doctors Union  
Room 901, Hang Shing Building,  
363-373 Nathan Road,  
Kowloon

Dear Dr. Ho,

Re: Hong Kong Doctors Union (“HKDU”)  
Ask Ms Janice Tse to step down from her office

I refer to your letters dated 19 and 26 September 2014 respectively, both reiterating the views of HKDU towards the proposed requirement of placing orders of drugs in written form. I am authorized to give you a reply.

We believe that patients' safety should always be the top priority of every stakeholder in the healthcare sector. For this reason, the requirements proposed by the Pharmacy and Poisons (Amendment) Bill 2014 (“the Bill”) as well as the requirement to place drug orders in written form which would be included in the Codes of Practice (“COPs”) for the respective licensed traders are to enhance the regulation of pharmaceutical products and relevant traders, with the ultimate objective to further enhance and protect patients' safety.

As we have repeatedly pointed out, the proposed requirement of written orders, as recommended by the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong (“Review Committee”) after comprehensive and thorough deliberation by its members, serves the policy objectives of protecting patients, fostering ethical conduct, as well as developing and maintaining high professional standards. You may wish to note that the Review Committee, which was tasked to strengthen the regulatory regime of pharmaceutical products in Hong Kong, comprises members from the pharmaceutical sectors, medical profession, academia, patient groups and consumer representatives. The Review Committee considers that the proposed requirement of written orders contributes to building up a complete set of record in the drug supply chain all the way from the primary source to the patients. It thus facilitates the tracing of source of drugs in the event of drug recall.

The recommendation could be ascribed to an incident involving a private doctor who mistakenly prescribed inappropriate medication to 153 patients over five months in 2005, resulting in serious and fatal consequences. The doctor concerned attributed such mistake to the delivery of incorrect drugs by the supplier who had erroneously taken the drug order placed verbally. In view of this, the Hong Kong Medical Association (“HKMA”), with over 10,000 members from all sectors of medical practice, published the “Good Dispensing Practice Manual” endorsed by the Medical Council of Hong Kong (“MCHK”) to all its members in July 2005 to enhance different procedures in drug dispensing and among others, it recommended orders for drugs to be made in writing via post or fax by the doctor and provided a sample order for doctor’s reference. In May 2007, the HKMA revised the “Good Dispensing Practice Manual” and it further recommended that the written orders be kept for checking by the doctor against the drugs delivered and for future reference. As regards the 2005 incident mentioned above, subsequent to a disciplinary inquiry in May 2009, the MCHK concluded that the private doctor concerned was guilty of misconduct.

The proposed requirement of written orders is supported by a wide spectrum of stakeholders including not only patient groups but also licensed traders and other industry / professional organizations which include the Alliance for Renal Patient’s Mutual Help Association, the Society for Community Organization, the Federation of Medical Societies of Hong Kong, the Hong Kong Pharmacology Society, and the Hong Kong Pharmaceutical Manufacturers Association. The Hong Kong Alliance of Patients’ Organizations Limited (“the Alliance”) reiterated its



support of the written order and the Bill in its recent meeting with the Administration in September 2014 at which the Alliance's Chairman and some 20 representatives of the Alliance's member organisations were present.

We would like to clarify once again that the ordering practice mentioned in your letter, i.e. doctors having to sign for delivered drugs, is already an existing statutory requirement for licensed wholesalers of poisons to support every sale or supply of Part I poisons with documents signed by the purchasers (including doctors). Such requirement is stipulated by existing Regulation 28 of the Pharmacy and Poisons Regulations (Cap. 138A) which requires all licensed wholesalers to support records of sales of Part I poisons with documents signed by the purchasers. In other words, the keeping of records of sales for Part I poisons supported by documents signed by the purchasers was already in place at the time when the 2005 incident mentioned in the paragraph above occurred and yet it was not sufficient to prevent the 2005 incident from happening. This is because the purchasers of Part I poisons, for example, registered medical practitioners, are not obliged to retain such documents. It is the seriousness of the 2005 incident, as well as the series of incidents relating to the safety of pharmaceutical products that took place between March and September 2009, that led to the comprehensive review on the drug ordering process by the Review Committee.

From 2011 to 2013, there were still a total of 9 cases which involved conviction registered against 11 doctors for failing to keep proper records of dangerous drugs. HKDU alleged in your letter of 19 September 2014 that "many of these doctors were young employees of Health Maintenance Organisations ("HMOs") which are not properly regulated by the government. HMOs order drugs in these employees' names and keep them ignorant." Contrary to your belief, all these doctors convicted were either the sole-proprietors or the directors of the companies operating the concerned medical clinics. Moreover, your allegation supports the need for written orders of drugs by the doctor himself so any order of the drugs in the doctor's name, as alleged, would be prevented.

HKDU has claimed that doctors could not order Ketamine as it is a forbidden drug and doubted our concern that dangerous drugs, such as anesthetics including Ketamine, were found in clinics without proper records. We wish to point out that Ketamine, such as Ketalar and Ketamine-hameln solution, is a registered pharmaceutical product in



Hong Kong, and Pfizer Corporation Hong Kong Limited and Mekim Limited are the respective holders of certificate of drug registration. Since Ketamine is also classified as dangerous drug under the Dangerous Drugs Ordinance (Cap. 134) ("DDO") and has been commonly abused by young people, it was cited as an example of dangerous drug to illustrate the importance of written order requirement to supplement the statutory requirements stipulated under the DDO. We have no intention to single out Ketamine but only to cite it as an example to show the need to tighten up the order and record keeping of dangerous drugs. Indeed, our concern goes beyond Ketamine to all types of dangerous drugs.

As we pointed out earlier, out of the 11 cases of convictions involving the registered medical practitioners, 9 cases involved dangerous drugs used as **anxiolytics and hypnotics** such as **Rohypnol** (street name as "**Cross**") and **Halcon** (street name as "**Blue Gremlin**) and Valium. In some cases, physical balance or particulars, such as the name and address of the supplier, invoice number, with respect to the quantity of dangerous drugs obtained were not recorded. As such, it would be difficult to trace the suppliers of the dangerous drugs. Also, some of these cases involving large quantity of dangerous drugs. You may wish to note that for 8 of the convicted cases involving benzodiazepines, the physical stock of certain benzodiazepines seized from the doctors' clinics were more than **1,000 tablets**. For two of the cases, the total quantity of diazepam tablets seized was more than **13,000 tablets**. Among the 5 cases involving phentermine, the total quantity of phentermine capsules seized from the doctors' clinics, in just 2 cases there were more than a staggering number of **19,000** and **28,000** capsules. The proposed written order can be an additional proof and protection for the doctors concerned since it serves to establish if such large quantity of dangerous drugs were ordered by the doctors themselves for clinical use, or ordered by someone else without their knowledge.

As such, the proposed written order requirements would serve to supplement the aforementioned legislative requirements in the case of dangerous drugs to ensure any orders for dangerous drugs are placed by authorized persons such as registered medical practitioners and help build up complete set of transaction records throughout the supply chain which is of great importance in the event of drug recalls as accurate and complete records would facilitate timely investigation during drug incidents. Furthermore, it would also help minimize errors during verbal ordering.



The requirement to place drug orders in written form would be implemented by phases to facilitate traders to adapt to the requirement. Initially, all drug traders licensed under the Pharmacy and Poisons Ordinance (Cap. 138) would be required by the respective COPs to place orders of Part I poisons, antibiotics and dangerous drugs in writing. In this respect, licensed drug traders are required to supply these drugs upon receipt of written orders, be they by fax, mail or electronic means. We note the HKDU's letter to the Legislative Council Members about the alleged delay of drug delivery resulting from written order system (para. 6 of your letter of 6 October 2014). HKDU clarified that "when we (you) talk about urgently needed drugs, we (you) are not talking about life saving situations. Such life threatening cases will always be referred to the A&E departments of the hospitals immediately. We (you) are worrying about the following situations such as patients with chronic illnesses e.g. hypertension who have to refill anti-hypertensive drugs; patients have to travel the next day and who require vaccination...etc."

We are pleased to note your support to our explanation that the written orders should not affect lifesaving treatment of patients. As regards to the situations of patients with chronic illness having to leave Hong Kong in a day or two, we have checked with the manufacturers and are given to understand that a written order as compared to a verbal order should not affect the delivery of drugs. Consideration would also be given to include any possible mechanism for licensed drug traders to supply these drugs to doctors who might urgently require the drugs for the purpose of medical treatment.

The Administration would closely monitor the implementation of requirement of written orders and consider extending the requirement to low-risk drugs such as Part II poisons and non-poisons pharmaceutical products at a later stage. We have also repeatedly emphasised that the Pharmacy and Poisons Board has already put in place a well-established mechanism to provide the trade and relevant stakeholders with various channels to participate in formulating, revising and issuing COPs and to express their views on such codes.

We are sure that medical practitioners would strive to assure quality of their professional practice with a view to providing quality services to their patients, and any measures that could serve to further protect patients' safety would be welcome and adopted by medical practitioners. In this regard, we strongly appeal to medical practitioners to order drugs from their suppliers in writing and keep such written orders

for verification upon delivery of the drugs and for future reference as one of the effective measures to protect patients' safety.

We have taken note of the points raised in your above letters. Once again, we thank the HKDU for its views towards the regulation of pharmaceutical products in Hong Kong. We trust that this reply, together with our previous replies provided to the HKDU on 15 July 2014 and 4 September 2014 respectively (Annexes I and II), have clearly set out the legitimate justifications for the introduction of written order in the COPs for the relevant licensed drug traders. There may be differences in stakeholders' views and we look forward to building consensus with the relevant stakeholders to safeguard the public health in Hong Kong.

Yours sincerely,



( Fiona Chau )

for Secretary for Food and Health

c.c. Private Secretary to Chief Executive  
(Attn: Mr Fred Chung, fax number: 2509 0580)

Legislative Council  
(Attn: Clerk to the Bills Committee on Pharmacy and Poisons  
(Amendment) Bill 2014)





Annex I

中華人民共和國香港特別行政區政府總部食物及衛生局  
Food and Health Bureau, Government Secretariat  
The Government of the Hong Kong Special Administrative Region  
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*Our Ref.:* FHB/H/19/69 Pt.4  
*Your Ref.:* HKDU/104/2014

*Tel No.:* 3509 8956  
*Fax No.:* 2840 0467

15 July 2014

Dr. Ho Ock Ling  
Hon. Secretary  
Hong Kong Doctors Union  
Room 901, Hang Shing Building,  
363-373 Nathan Road,  
Kowloon

Dear Dr. Ho,

Re: Hong Kong Doctors Union ("HKDU")  
Ask Ms Janice Tse to step down from her office

I refer to your letter dated 27 June 2014 relaying the views of HKDU towards the Pharmacy and Poisons (Amendment) Bill 2014 ("the Bill").

Needless to say, patients' safety is of the foremost importance to both the Government and healthcare professionals. As you would appreciate, the requirements proposed by the Bill to enhance the regulation of pharmaceutical products and relevant traders, including the proposed requirement of written order of drugs, are measures with the ultimate objective to further enhance and protect patients' safety. The patient groups as well as other industry / professional organisations, such as the Alliance for Renal Patient's Mutual Help Association and the Society for Community Organization, the Federation of Medical Societies of Hong Kong, the Hong Kong Pharmacology Society, and the Hong Kong Pharmaceutical Manufacturers Association are of the view that the

proposed requirement of the written order of drugs will offer greater protection for patients.

As we have pointed out on several occasions, in 2005, a private doctor mistakenly prescribed inappropriate medication to 153 patients over a period of five months, resulting in serious and fatal consequences. The doctor concerned attributed such mistake to the delivery of incorrect drugs by the supplier who had erroneously taken the drug order placed verbally. Subsequently, the Hong Kong Medical Council decided in May 2009 that the private doctor had failed to take adequate steps to verify whether the drugs received from the supplier corresponded to the order and failed to ensure accuracy of the prescriptions given to patients, and thus ruled that the private doctor was guilty of misconduct. In the light of the seriousness of that incident, as well as the series of incidents relating to the safety of pharmaceutical products that took place between March and September 2009, the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong ("the Review Committee") published a report in December 2009 to put forth 75 recommendations, including the requirement of written orders of drugs, with a view to avoiding the problems observed in the aforementioned drug incidents.

Specifically, the Review Committee considers that the proposed requirement of the written order of drugs would not only facilitate the tracing of source of drugs in the event of drug recall and the taking of swift and appropriate remedial actions in case of adverse incidents, but also deter the sale of unregistered drugs and purchase of drugs from unregistered traders as these unlawful acts do not have the support of written orders.

Indeed, the Dangerous Drugs Regulations (Cap. 134A) ("DDR") already requires medical practitioners to keep a register of every quantity of dangerous drugs obtained or supplied by him, in the form and manner stipulated under Regulation 5 and Regulation 6 of the DDR. From 2011 to 2013, a total of 11 registered medical practitioners were convicted of offences related to contravention of Regulation 5 of the DDR, i.e. failing to keep any records of dangerous drugs or failing to keep the records in accordance with the format specified in the first schedule of the DDR. The dangerous drugs involved in these convictions include:

- (i) 9 cases involving benzodiazepines, which are used as anxiolytics and hypnotics (including drugs with abuse potential, such as Rohypnol (street name as "Cross"), Halcion (street name as "Blue Gremlin") and Valium);



- (ii) 5 cases involving phentermine, which are used for weight reduction or the treatment of obesity; and
- (iii) 1 case involving opioids analgesics, which are used for alleviating pain (such as methadone and morphine).

We are sure that medical practitioners would strive to assure quality of their professional practice with a view to providing quality services to their clients, and any measures that could serve to further protect patients' safety would be welcome and adopted by medical practitioners. In this regard, we strongly appeal to medical practitioners to order drugs from their suppliers in writing and keep such written orders for verification upon delivery of the drugs and for future reference as one of the effective measures to protect patients' safety.

Besides minimising errors in the process of ordering and delivering drugs, the proposed requirement would also help build a complete set of transaction records to facilitate the tracing of drugs in order to effectively plug the existing loophole that the regulatory authority is unable to trace drugs coming from unknown sources in some cases due to the lack of written records.

We thank the HKDU for its concerns towards the regulation of the pharmaceutical industry in Hong Kong, and look forward to further collaboration with the medical profession to safeguard the public health in Hong Kong.

Yours sincerely,



( Richard Yuen )  
Permanent Secretary for Health



Annex II

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

*Our ref.:* LM to FHB/H/19/69 Pt.4  
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*Tel no:* 3509 8915  
*Fax no:* 2840 0467

4 September 2014

Dr Ho Ock Ling  
Hon. Secretary  
Hong Kong Doctors Union  
Room 901, Hang Shing Building  
363 - 373 Nathan Road  
Kowloon

Dear Dr Ho,

Hong Kong Doctors Union ("HKDU")  
Ask Miss Janice Tse to step down from her office

I refer to your letter dated 1 August 2014, relaying the views of HKDU towards the Pharmacy and Poisons (Amendment) Bill 2014 ("the Bill") and including 219 signed petition letters, to the Chief Executive. The Chief Executive has asked me to reply on his behalf.

As we have pointed out on several occasions, a private doctor mistakenly prescribed inappropriate medication to 153 patients over a period of five months in 2005, resulting in serious and fatal consequences. The doctor concerned attributed such mistake to the delivery of incorrect drugs by the supplier who had erroneously taken the drug order placed verbally. Subsequently, the Hong Kong Medical Council decided in May 2009 that the private doctor had failed to take adequate steps to verify whether the drugs received from the supplier corresponded to the order and failed to ensure accuracy of the prescriptions given to patients, and thus ruled that the private doctor was guilty of misconduct.



We would like to clarify that the ordering practice mentioned in your letter, i.e. doctors having to sign for delivered drugs, is indeed a statutory requirement for licensed wholesalers of poisons to support every sale or supply of Part I Poisons with documents signed by the purchasers (including doctors). As a matter of fact, the use of invoice and a poison form for record keeping of Part I Poisons, was already in place at the time when the 2005 incident mentioned in the paragraph above occurred, yet it was not sufficient to prevent the 2005 incident from happening. To prevent recurrence of similar incidents, the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong ("Review Committee") has recommended to, among the 75 recommendations made in its report published in December 2009, put in place the requirement of placing drug orders in written form with a view to facilitating sellers and buyers of drugs to verify if the drugs delivered are actually the drugs ordered. This would also contribute to the building up of a complete set of drug transaction records, thus facilitating the tracing of source of drugs and minimizing errors in the placing / accepting drug orders, as well as delivery and receipt of drugs, so as to provide the best protection to the public. This is also in line with the recommendation of Hong Kong Medical Association as promulgated in the Good Dispensing Practice and overseas guidelines.

The patient groups as well as other industry / professional organisations, such as the Alliance for Renal Patient's Mutual Help Association and the Society for Community Organization, the Federation of Medical Societies of Hong Kong, the Hong Kong Pharmacology Society, and the Hong Kong Pharmaceutical Manufacturers Association are of the view that the proposed requirement of the written order of drugs will offer greater protection for patients.

We note that in addition to mail and fax, electronic means such as email and textual messages are also common forms of written communications / records nowadays. In order to facilitate doctors and traders to implement the proposed requirement of placing drug orders in written form, the Pharmacy and Poisons Board would also accept retainable records in electronic means as a form of written orders. With the availability of various means, we trust that the use of written orders would not undermine the efficiency in ordering drugs. In this regard, we note that the Hong Kong Association of the Pharmaceutical Industry has opined that written orders could be handled as efficiently as verbal orders, and would not cause delay in drug delivery.

It is also noteworthy that the Review Committee considers that the proposed requirement of the written order of drugs would not only facilitate the tracing of source of drugs in the event of drug recall and the taking of swift and appropriate remedial actions in case of adverse incidents, but also deter the sale of unregistered drugs and purchase of drugs from unregistered traders as these unlawful acts do not have the support of written orders. By building a complete set of transaction records, and thus facilitating the tracing of drugs, this would also help effectively plug the existing loophole that the regulatory authority is unable to trace drugs coming from unknown sources in some cases due to the lack of written records. To this end, we would like to reiterate once again that the Government spares no effort to combat illegal trading of drugs in order to uphold the safety of the general public.

Patients' safety is of the foremost importance to both the Government and healthcare professionals. The Government strongly appeals to medical practitioners, in the public interest to protect patients' safety, to order drugs from their suppliers in writing and keep such written orders for verification upon delivery of the drugs and for future reference.

Once again, we thank the HKDU for its concerns towards the regulation of the pharmaceutical industry in Hong Kong, and look forward to further collaboration with the medical profession to safeguard the public health in Hong Kong.

Yours sincerely,



( Fiona Chau )

for Secretary for Food and Health

c.c. Private Secretary to Chief Executive  
(Attn: Mr Fred Chung) Fax No. 2509 0580