



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

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3 July 2014

Prof Hon Joseph LEE Kok-long
Chairman
Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014
Legislative Council Complex
1 Legislative Council Road
Central, Hong Kong

Dear Prof Hon LEE,

Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014
Written Questions Raised by Hon Vincent FANG

We refer to Hon Vincent FANG's letter to the Chairman dated 16 June 2014 raising questions on the Pharmacy and Poisons (Amendment) Bill 2014 ("the Bill"). In response to the Hon FANG's concerns, which include a series of drug incidents in 2009, the drafting process and consultation work of the Bill, and the arrangements for various codes of conduct ("COC") / codes of practice ("COPs"), the Administration would like to provide in this letter the relevant information to the Chairman and Members. In fact, most of the information has already been detailed in the Administration's papers or written responses submitted earlier on to the Legislative Council ("LegCo") Panel on Health Services ("HS Panel") and/or the Bills Committee.

The series of drug incidents in 2009 and measures taken by the Administration

2. In response to Hon Vincent FANG's queries about drug incidents, as mentioned in the paper we submitted to the HS Panel in December 2013 (see Annex 1), 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. Subsequently, in May 2009, the Hong Kong Medical Council decided 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 and 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 ("Review Committee") published a report in December 2009 (see paragraph 3 below) 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. Annex G to the report of the Review Committee (reproduced at Annex 2) sets out a summary of the incidents in 2009 and the immediate follow-up actions taken by the Administration in response to individual incidents. As pointed out in the LegCo Brief¹ we issued on the Bill, in response to the drug incidents in early 2009, the Government immediately set up the Review Committee in March of the same year to conduct a comprehensive review of the existing regulatory regime for pharmaceutical products. The Review Committee was chaired by the Permanent Secretary for Food and Health (Health) and comprised of members from various sectors, including the pharmaceutical sector, medical profession, academia, patient groups and consumer representatives. The lists of members of the Review Committee and its two Subcommittees are set out in items (a) to (c) of Annex 1 to LegCo Paper No. CB(2)1543/13-14(01) which we submitted to the Bills Committee on 16 May 2014.

3. After in-depth examination, the Review Committee published a report in December 2009, putting forth a total of 75 recommendations to enhance the regulation of pharmaceutical products and protection of public health. The Administration submitted the report to the HS Panel in January 2010². A summary of the 75 recommendations was reproduced in Annex B to the LegCo

¹ Please refer to the LegCo Brief issued by the Food and Health Bureau on 19 March 2014 (File No.: FHB/H/23/1 Pt. 9).

² Please refer to LegCo Paper No. CB(2)680/09-10(03) issued by the Food and Health Bureau on 11 January 2010.

Brief on the Bill for Members' reference. As pointed out in the aforementioned LegCo Brief, in order to carry out the Review Committee's recommendations as soon as possible, the Administration has implemented in phases the 59 recommended measures which do not require legislative amendments. We briefed the HS Panel on the progress of implementing these 59 recommendations in November 2013³ (please refer to Annex 3 for the latest progress).

4. The primary objective for introducing the Bill is to implement the rest of the Review Committee's recommendations which require amendments to the existing Pharmacy and Poisons Ordinance (Cap. 138) ("the Ordinance") and its subsidiary legislation. Please refer to the ensuing paragraphs for details.

Drafting of the legislative proposal and consultation work

5. To assess the impacts of the remaining 16 recommendations of the Review Committee (which could only be implemented after making legislative amendments) on drug traders and stakeholders and to ensure transparency of the legislative process, the Administration commissioned a consultant in January 2011 to conduct a Regulatory Impact Assessment ("RIA"). We have presented in detail the consultation work of the RIA⁴ at the second meeting of the Bills Committee. The assessment methods included soliciting stakeholders' views at consultation meetings and workshops, and gauging public sentiments on the proposed legislative amendments through a public opinion survey carried out by the University of Hong Kong. From February to March 2011, the consultant held a total of 24 in-depth consultation meetings and 12 interactive workshops with the major stakeholders (the list is at Annex 4), and completed the RIA report in January 2013. After considering the results of the RIA and the views of stakeholders, the Administration proceeded with the drafting of the Bill and briefed the HS Panel about the relevant proposed legislative amendments at its meeting held in November 2013. Subsequently, in response to the views of some Members of the HS Panel and organisations with representatives attending the special meeting of the HS Panel held in December 2013, we adjusted the content of the proposed legislative amendments with a view that the majority of the measures set out in the 16 recommendations (please refer to Annex C to the aforementioned LegCo Brief for details) could be implemented to strengthen the regulatory mechanism on pharmaceutical products and drug traders without posing serious impacts on various parties. Three months later, we introduced the Bill into the LegCo on 26 March 2014.

³ Please refer to Annex B to LegCo Paper No. CB(2)254/13-14(03) issued by the Food and Health Bureau on 18 November 2013.

⁴ Please refer to the LegCo Paper No. CB(2)1543/13-14(01) issued by the Food and Health Bureau on 16 May 2014.

Recommendations and measures to reduce drug incidents

6. The supply chain of pharmaceutical products covers a wide range of areas, including manufacturing, import/export, wholesale and retail of pharmaceutical products. To prevent drug incidents effectively, targeted regulatory measures must be put in place for every segment of the supply chain. To this end, the objective of the Review Committee in putting forth 75 recommendations is to introduce improvement measures targeting at each segment of the supply chain of pharmaceutical products. Among them, the 59 recommendations not requiring legislative amendments, which have been implemented or are to be implemented, include the following measures which help reduce drug incidents:

- To impose more stringent requirements for microbiological monitoring in the manufacturing process of local drug manufacturers;
- To increase the number of inspections to licensed drug manufacturers and licensed/listed drug traders;
- To shorten the time for processing applications for registration of pharmaceutical products;
- To enhance the tracking of import and export of unregistered drugs;
- To upgrade the central inventory monitoring computer system of the Department of Health ("DH") so as to enhance the traceability of drugs;
- To require the drug suppliers of the DH and the Hospital Authority to provide additional information, such as pack size and registration number, in the delivery documents so as to enable more effective physical checking, and to facilitate verification to see if the drugs received are legally conforming;
- To improve pharmacovigilance measures (including regular issue of pharmacovigilance bulletins), and to adopt a risk-based approach in drug recall and public communication; and
- To provide more information about drug safety in the website of the Drug Office.

7. Apart from the above 59 recommendations which do not involve legislative amendments, we will, through the amendments proposed under the Bill, implement the other recommendations of the Review Committee which require legislative amendments. These recommendations can also enhance the overall regulation of pharmaceutical products as well as traders and registered pharmacists in the supply chain of such products. Apart from minimising drug incidents, the recommendations also improve the Government's ability to trace the source of the problems when there are drug incidents. The relevant clauses of the Bill are as follows:

- Clause 4 of the Bill: The repackaging of pharmaceutical products must be carried out by licensed manufacturers and therefore must comply with the regulatory requirements to be fulfilled by licensed manufacturers (including the keeping of records);
- Clause 45 of the Bill: To expand the current control over the wholesale of poisons to cover all pharmaceutical products (including poisons and non-poisons); and
- Clause 48 of the Bill: Wholesalers must keep transaction records of all pharmaceutical products (including poisons and non-poisons) which must include the required additional particulars (such as the batch number and pack size of pharmaceutical products).

8. Moreover, the Bill proposes to empower the Pharmacy and Poisons Board (“PPB”) to prepare relevant COPs for the drug traders concerned (including manufacturers, wholesalers and retailers). Such COPs will cover various requirements that will help prevent drug incidents, such as the relevant drug traders are required to place/accept drug orders in written form; authorized and listed sellers of poisons are required to purchase pharmaceutical products only from licensed drug traders (manufacturers and/or wholesale dealers); and authorized and listed sellers of poisons are required to keep relevant supporting documents, such as sales invoices related to every purchase of all pharmaceutical products.

9. We consider that the incorporation of the requirement of placing drug orders in written form into the COPs for relevant drug traders is an essential step for preventing drug incidents. If written records are available when placing drug orders, the relevant suppliers and corresponding parties will not only be able to check the orders upon delivery and receipt of drugs, but more importantly, the Administration will be able to trace the source of the problem from the written records and take corresponding measures to safeguard public health in the event of drug incidents. For incidents concerning incorrect dispensing of drugs, as they involve professional conduct of healthcare professionals (including registered pharmacists and medical practitioners), regulatory actions will be taken by the regulatory authorities of the respective healthcare professions (such as the PPB and the Medical Council of Hong Kong). Currently, in the Good Dispensing Practice Manual issued by the Hong Kong Medical Association in 2007, healthcare professionals are reminded to explain to the patient or his/her agent the details about the correct use of the medicines when dispensing medicines to a patient. Besides, patients should also follow the directions of healthcare professionals when taking medicines and seek medical advice if in doubt.

Arrangements for COC/COPs

10. Hon Vincent FANG also enquired whether the PPB would submit the COC/COPs formulated for registered pharmacists and relevant drug traders to the Bills Committee or relevant LegCo Panel for perusal or reference. We would like to clarify that while the Bill proposes empowering the PPB to issue or revise COC/COPs, the contents of the COC/COPs are NOT part of the legislation or its subsidiary legislation. The Ordinance and its subsidiary legislation form a comprehensive regulatory framework for pharmaceutical products, relevant drug traders and registered pharmacists whereas the COC/COPs formulated by the PPB provide practical guidance for the trade in respect of the Ordinance and its subsidiary legislation. As the contents of the COC/COPs are **NOT** part of the legislation or its subsidiary legislation, no one will be deemed to have violated the Ordinance or its subsidiary legislation simply because he/she has contravened the COC/COPs (unless the matter concerned constitutes an offence under the Ordinance or its subsidiary legislation). The PPB has put in place a mechanism to extensively consult the relevant stakeholders when formulating or revising the relevant codes. For details of the consultation work, please refer to LegCo Paper No. CB(2)1543/13-14(01) we submitted to the Bills Committee on 16 May 2014. Moreover, as proposed in Clause 6 of the Bill, if a COC/COP is issued or revised, the PPB must identify the code or the part revised and the date on which the code or revision is to take effect in a Gazette notice. The PPB will, at the same time, write to inform the relevant licensed drug traders/registered pharmacists of the issue or revision of the COC/COPs concerned.

11. As we have mentioned in items 14 to 19 in the table attached to LegCo Paper No. CB(2)1522/13-14(01) submitted to the Bills Committee on 16 May 2014, some existing ordinances also empower the relevant authorities to issue COPs, such as section 3 of the Broadcasting Ordinance (Cap. 562) and section 67 of the Insurance Companies Ordinance (Cap. 41). In view of the nature of COC/COPs to give practical guidance, we are of the view that we should take reference to the practice of the aforementioned legislation and empower the PPB to formulate and revise the COC/COPs. This will provide the PPB with the flexibility to draw up or revise the relevant codes with regard to local circumstances and changes.

12. Currently, staff of the DH are authorised to make the necessary examinations and inquiries when conducting inspections to authorized sellers of poisons ("ASPs"). However, the existing legislation does not require the ASPs to keep stock of poisons and pharmaceutical products (including prescription medicines) or to retain any information relating to the order or receipt of pharmaceutical products. Hence, the revised COP for ASPs will require the ASPs to place/accept drug orders in written form and keep the relevant records, as well as to retain all the supporting documents.

13. We would like to thank Members and various deputations for their concerns and comments about the Bill. We also understand that the trade has different views towards the measures for enhancing the regulatory framework. The purpose of the Bill is to offer better protection for public health. In drafting the Bill, we have strived to strike a balance among the interests of the trade, various stakeholders and the public, with a view to strengthening the regulation of the pharmaceutical trade without causing unnecessary impacts on the trade.

Yours sincerely,



(Miss Fiona CHAU)
for Secretary for Food and Health

**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
December 2013**

Chronology of Drug Incidents from March to September 2009

Date	Details of Incident
6 March	The University of Hong Kong announced that four batches of Allopurinol tablets produced by a local manufacturer, Europharm Laboratoires Co. Ltd. were contaminated with <i>Rhizopus microsporus</i> . HA announced replacement of the drug for affected patients from 8 March 2009. On 9 March, DH ordered Europharm to recall all Allopurinol tablets from the market as laboratory analysis of the samples of the affected four batches of Allopurinol confirmed the presence of <i>Rhizopus</i> . DH investigation revealed that during the production process, there was prolonged storage of granules prior to tableting. Europharm voluntarily stopped production and distribution of all products.
11 March	DH instructed Marching Pharmaceutical Ltd., a local manufacturer, to recall a total of 216 pharmaceutical products as the label expiry dates of these products were not substantiated by laboratory data. On 12 March, the Manufacturers Licensing Committee of the Pharmacy and Poisons Board suspended the licence of the company for one month. The case had also been reported to the police as during the course of DH investigations, certain irregularities in the documents submitted by the company were found.
16 March	DH investigation found that part of the pharmaceutical products, metformin tablets packed in 50x10's blister, supplied to HA by a local manufacturer, Christro Pharmaceuticals Ltd., was not registered with DH. HA announced replacement of the drug for affected patients from 17 March 2009.
19 March	DH investigation found that Unipharm Trading Company, a licenced wholesaler with no drug manufacturing licence, conducted unlicensed packaging of Amitriptyline tablets. DH ordered the company to recall the product.

Date	Details of Incident
20 March	DH investigation found that the expiry dates of two batches of Cosalgescic tablets imported by Unipharm Trading Company had been tampered. The correct expiry dates of the concerned batches should be May 2009 and June 2009 respectively, but they had been changed to June 2010. DH would report the case to the police for investigation. Unipharm initiated product recall at consumer level.
22 March	HA announced that staff of Yaumatei Jockey Club General Out-patient Clinic dispensed expired cough medicine, Promethazine Co Linctus, to around 10 out of 250 patients prescribed with this drug during 1 February to 20 March. HA made arrangements for replacement of the drug for affected patients.
	DH received report from HA that the actual volume of two batches of "Water for injections" imported by Luen Cheong Hong Ltd., a licenced wholesaler, exceeded the volume of 100 ml on the product label by 30 ml. The product was manufactured by the Indonesian subsidiary of a Japanese company, Otsuka. Luen Cheong Hong initiated product recall from HA. The product was not available in private market.
27 March	In response to media enquiries, HA replied that a leukemia female patient in Prince of Wales Hospital received two doses of 4 grams of Cytarabine instead of the correct quantity of 2 grams on 24 March on the first day of a five-day chemotherapy treatment. Staff later became aware of the mistake and doctor immediately assessed the patient; the patient was in stable condition.
2 April	DH investigation found that Mentholatum Pain Patch supplied by Mentholatum (Asia Pacific) Ltd., a licensed wholesaler, was unregistered. Mentholatum applied for registration of the product in 2005 but the application was yet to be approved. DH instructed Mentholatum to recall the product at retail level. There was however no immediate safety or quality concern over the use of the product.

Date	Details of Incident
4 April	DH investigation found that a product named Viscotears supplied by Novartis Pharmaceuticals (Hong Kong) Ltd., a licenced wholesaler, was not yet registered. DH instructed Novartis to recall the product from the market. There was however no immediate safety or quality concern over the use of the product.
6 April	DH investigation found that the registration of a product named Cortiphenol H Eye ointment 2.5g supplied by Novartis Pharmaceuticals (Hong Kong) Ltd. had been expired in December 2007. DH instructed Novartis to recall the product from the market. There was however no immediate safety or quality concern over the use of the product.
	Hind Wing Company Ltd., a licensed wholesaler, initiated a consumer-level recall of two batches of Dithrasal ointment, Dithrasal ointment and Dithrasal ointment 2%, as they were found containing a higher than permitted level of 1,8 dihydroxyanthraquinone (DHAQ) by the Australian drug authority.
	DH investigation found that five pharmaceutical products supplied by Main Life Corporation Ltd., a licensed wholesaler, were unregistered. DH instructed Main Life to recall the products from the market. There was however no immediate safety or quality concern over the use of the product.
11 April	Tung Wah Hospital announced that during a routine check of Phenobarbitone tablets before issuing to the ward on 8 April, it was discovered that Phenobarbitone 60 mg tablets were pre-packaged instead of the intended Phenobarbitone 30 mg tablets on 17 March, resulting in the intake of double dosage of the medication by 6 in-patients. One of the concerned patients passed away on 10 April while the remaining 5 patients were in stable condition.
18 April	In response to media enquiries, HA replied that staff of Lady Trench General Out-patient Clinic mixed up diabetes tablets with drugs for controlling high blood pressure for

Date	Details of Incident
	at least 63 diabetes patients on 17 April.
21 April	DH investigation found that the product insert of Funginox Solution imported by Deltpharm Ltd., a licenced wholesaler, contained unregistered indications and treatment duration. DH instructed Deltpharm to recall the product from the market. There was however no immediate safety or quality concern over the use of the product.
22 April	The pharmacy of Kennedy Town Jockey Club Clinic found black spots on some tablets in a bottle of diuretic drug (Frusemide 40 mg) supplied by Vickmans Laboratories Ltd., a licensed wholesaler, on 15 April. HA Head Office carried out a random check on other batches of Frusemide 40mg and found out that some tablets of another batch also had black spots. According to initial findings, the black spots were confirmed as contamination by fungal species asperigillus. HA announced replacement of the drug for affected patients from 8 March 2009. The Manufacturers Licensing Committee suspended the license of Vickmans with immediate effect for non-compliance with GMP standards on 22 April. DH also instructed Vickmans to conduct a consumer level recall of the product.
28 April	Pfizer Corporation Hong Kong Ltd., a licenced wholesaler, recalled a product Lignocaine HCl Injection 1% from the market as one bottle in a ten-bottle pack of the product was found to be labeled as Sodium Chloride Intravenous Infusion 0.9%. The product was manufactured and packed in Australia, without further repackaging after import into Hong Kong.
6 May	In an internal review, Zuellig Pharma Ltd., a licensed wholesaler, found that Milupa GES 45 Oral Rehydration Salts Sachet was not registered. The product was manufactured in Germany and was once registered in Hong Kong from 1989 to 2004. However, the registration holder did not renew the product registration

Date	Details of Incident
	after its expiry in 2004. Zuellig initiated a recall of the product.
7 May	<p data-bbox="491 421 1342 741">DH investigation found that the registration of a drug Povidone-iodine Prep Pad imported by Luen Cheong Hing Ltd., a licenced wholesaler, had expired in October 2008, but Luen Cheong Hong was still selling the product. DH instructed Luen Cheong Hong to recall the product from the market. There was however no immediate safety or quality concern over the use of the product.</p> <p data-bbox="491 790 1342 1055">During a DH investigation, Hitpharm Pharmaceutical Company Ltd., a licensed wholesaler, was found selling 46 pharmaceutical products in unapproved sales packages with unapproved label information. DH instructed Hitpharm to recall the unregistered products from the market.</p>
2 September	DH investigation found that Jacobson Medical (Hong Kong) Ltd., a licensed wholesaler, had sold the product Tylenol in unapproved sales packages with unapproved label information. Jacobson initiated a recall of the product. There was however no immediate safety or quality concern over the use of the product.
28 September	DH investigation found that a series of 17 pharmaceutical products imported by Dragon Link (International) Trading Company Ltd., a licensed wholesaler, contained 10mg of the mineral manganese instead of 5mg as per the product label. Dragon Link initiated a recall of the affected products.

**Summary on the Progress of the Implementation of the
Recommendations by the Review Committee
on the Regulation of Pharmaceutical Products in Hong Kong
("Review Committee")**

The Department of Health ("DH") has been actively implementing the 75 recommendations of the Review Committee to raise the standards of the pharmaceutical industry and enhance the regulation of pharmaceutical products. Accordingly, the DH established the Steering Committee on the Regulation of Therapeutic Products, chaired by the Deputy Director of Health of the DH, on 20 January 2010 to oversee the implementation of the recommendations of the Review Committee. Besides, the DH also set up seven working groups to oversee the implementation progress.

2. Among the 75 recommendations put forward by the Review Committee, 16 recommendations require amendments to the existing Pharmacy and Poisons Ordinance (Cap. 138) and its subsidiary legislation.

3. For the rest of the recommendations, 35 recommendations have already been implemented, including:

- setting up a Drug Office in the DH and headed by Assistant Director (Drug) in September 2011;
- raising the requirements of microbiological monitoring in the manufacturing process of local drug manufacturers;
- raising the experience requirement of authorized persons of local drug manufacturers;
- stepping up inspection on drug manufacturers and licensed/ listed drug traders;
- shortening the processing time for application for drug registration;
- enhancing the tracking of import and export of unregistered drugs;
- requiring the drug suppliers of the DH and Hospital Authority to provide more information when delivering drugs (such as the pack size and registration number in order to facilitate effective checking of the actual products) and to facilitate the verification to see if the drugs received are legally conforming;
- improving pharmacovigilance measures (including regular publication of pharmacovigilance bulletin) and adopting a risk-based approach in drug recall and public communication; and

- providing more information on drug safety on the website of the Drug Office.

4. Another six recommendations which are related to Hospital Authority's measures to ensure the continuity of supply, safety and quality of drugs procured and to improve the storage and inventory monitoring system have also been implemented.

5. The remaining 18 recommendations are being implemented, five of which are related to the upgrade of the Hong Kong Good Manufacturing Practice standard to PIC/S standard¹ so as to be on par with international best practice. In this regard, DH has commissioned a two-year consultancy starting from August 2012 which would be completed in August 2014. With regards to the recommendation of formulating a set of formal qualification requirements for authorized persons and liaising with relevant universities for setting up structural training programme for authorized persons, the DH and its consultant are now drawing up the relevant requirements, including, inter alia, holding recognised university qualifications and completion of courses relating to pharmaceutical manufacturing. It is expected that details of the relevant approval system will be submitted to the Pharmacy and Poisons Board for consideration and announced to the public within this year.

6. The rest of the recommendations are on-going, including the preparation of Codes of Practice/ Code of Conduct for various licensed and listed drug traders and registered pharmacists; enhancement of the central inventory monitoring computer system of the DH and drugs database on the DH website; the implementation of BABE studies² as registration requirement for pharmaceutical products by phases; promotion of pharmacovigilance activities and review of the effectiveness of the improved pharmacovigilance measures etc.

¹ PIC/S standard refers to the standard promulgated in the "Guide to Good Manufacturing Practice for Medicinal Products" and its annexes (where applicable) published by the Pharmaceutical Inspection Cooperation Scheme.

² BABE refers to "bioavailability and bioequivalence", and is the therapeutic equivalence of the same pharmaceutical product manufactured by different manufacturers. BABE studies seek to assess whether a generic drug produces the same therapeutic effect as the patent drug.

**List of stakeholders participating in Consultation Meetings
conducted under the Regulatory Impact Assessment**

Group of stakeholders		Stakeholder interviewed
1	Pharmaceutical manufacturers	Hong Kong Pharmaceutical Manufacturers Association
2	Pharmaceutical importer & exporters/ wholesalers/ distributors	Hong Kong Suppliers Association
		Major distributor – DKSH
		Major distributor – LF Asia
		Major distributor – Zuellig Pharma
		The Hong Kong Association of the Pharmaceutical Industry
		The Hong Kong Medicine Dealers Guild *
		The Pharmaceutical Distributors Association of Hong Kong
3	Pharmaceutical retailers	Hong Kong General Chamber of Pharmacy Limited
		The Direct Selling Association of Hong Kong
		The Hong Kong Health Food Association
		The Cosmetic and Perfumery Association of Hong Kong
		Federation of Beauty Industry Hong Kong
4	Pharmacists	The Practising Pharmacists Association of Hong Kong
		The Society of Hospital Pharmacists of Hong Kong
		The Pharmaceutical Society of Hong Kong
5	Medical / veterinary professionals	Hong Kong Academy of Medicine *
		Hong Kong Doctors Union
		Hong Kong Medical Association
		China (Hong Kong) Veterinary Association *
		Hong Kong Veterinary Association *
6	Hospital groups	Hospital Authority
		The Hong Kong Private Hospitals Association
7	Government department	Customs and Excise Department *
		Government Laboratory
8	Academics	The School of Pharmacy, The Chinese University of Hong Kong

Group of stakeholders		Stakeholder interviewed
		Faculty of Medicine, The Chinese University of Hong Kong *
		Li Ka Shing Faculty of Medicine, University of Hong Kong *
9	Patients/ consumers	Alliance for Renal Patients Mutual Help Association
		Care of your Heart – Cardiac Patients Mutual Support Association
		Consumer Council

* Through written consultation