Our ref. 本署檔號： DH PS/7-45/14 II
Your ref. 來函檔號： CB(3)/PAC/R53

22 January 2010

Legislative Council
Legislative Council Building
8 Jackson Road, Central
Hong Kong
(Attn: Ms Miranda HON, Clerk
Public Accounts Committee)

Dear Ms HON,

**The Director of Audit's Report on the results of value for money audits (Report No. 53)**

**Control of western medicines (Chapter 5)**

I refer to your letter dated 29.12.2009 on the above subject and wish to respond as follows -

(a) the number of convictions related to unregistered medicines and the penalties imposed by the courts in the past three years were as follows -

| Year | No. of Convictions | Penalties |
|---|---|---|
| 2007 | 39 | Fines ranging from $1,000 to $75,000. In one case, a two-month imprisonment suspended for two years was added on |

**Department of Health**
Wu Chung House, 21st Floor,
213 Queen's Road East,
Wan Chai, Hong Kong.
Telephone: 2961 8888
Fax: 2836 0071

衞生署
香港灣仔皇后大道東 213 號胡忠大廈 21 樓
電話： 2961 8888
圖文傳真： 2836 0071

***We are committed to providing quality client-oriented service***

| | | |
|---|---|---|
| | | top of a $10,000 fine. In another case, a four-month imprisonment suspended for two years was imposed on top of a $10,000 fine. |
| 2008 | 34 | Fines ranging from $1,000 to $20,000. In one case, a four-week imprisonment suspended for two years was imposed instead of a fine. In another case, a two-week imprisonment suspended for one year was imposed on top of a $8,000 fine. |
| 2009 | 28 | Fines ranging from $1,000 to $20,000. |

The policy of the Pharmacy and Poisons Board in relation to licensees convicted of offences related to unregistered medicines is at Annex 1;

(b) the Chief Pharmacist has informed me that the proposal of devising a computer system to monitor the import and export of medicines made in 1999 was opposed by small to medium size pharmaceutical importers/exporters. The reason for the opposition was that many companies still did not use computers in their day-to-day operations, and that to mandate the use of computers to submit import and export licence applications would post operational difficulties. Some of these importers/exporters subsequently formed the Pharmaceutical Distributors Association of Hong Kong, which currently has a membership of about 50 small to medium size companies;

(c) the Chief Pharmacist has drawn up a list of suggestions that he had made in the past 10 years for tightening up control of importation of unregistered medicines for re-export purposes. The list is attached at Annex 2.

(d) the numbers of licence applications approved and refused in the past three years were as follows -

| | ASPs | | LSPs | |
|---|---|---|---|---|
| Year | No. of Applications Approved | No. of Applications Refused | No. of Applications Approved | No. of Applications Refused |
| 2007 | 39 | 0 | 311 | 0 |
| 2008 | 35 | 0 | 572 | 1 |
| 2009 | 57 | 0 | 337 | 1 |

The reason for refusal of the two cases in 2008 and 2009 was that the applicant concerned did not meet the established licensing requirements of any person involved in the ownership or operation of the applicant company having had one conviction related to unregistered medicines, drugs of abuse or counterfeit drugs in the past three years, or two convictions of other drugs in the past three years.

(e) I also attach herewith a copy of the report of the Review Committee.

Yours sincerely,

(Dr P Y LAM)
Director of Health

c.c Secretary for Food and Health (Attn : Ms Shirley LAM) (Fax no. 2526 3753)
Government Chemist (Fax no. 2715 5626)
Secretary for Financial Services and the Treasury
(Attn : Miss Katy FONG) (Fax no. 2147 5239)
Director of Audit (Fax no. 2583 9063)
Secretary for Civil Service (Attn : Ms Jenny CHOI) (Fax no. 2530 5827)

Annex 1

**Policy of the Pharmacy and Poisons Board in relation to licensees convicted of offences related to unregistered medicines**

**Before November 2000 (extracted from minutes of meeting of the Board)**

Against authorized sellers of poisons (i.e. ASPs, or dispensaries)

(a) a disciplinary inquiry would be held if an ASP or any of its personnel:

(i) had been convicted of an offence involving the sale of psychotropic drugs or other drugs of abuse or the sale or possession of counterfeit drugs; or

(ii) had had a previous conviction within the last three years;

(b) in all other cases, the proprietor/director and the pharmacist of the ASP would be interviewed by the Chief Pharmacist and the Board's Secretary to give them a verbal caution.

Against listed sellers of poisons (i.e. LSPs, or medicine companies)

(a) an LSP would be removed from the List of LSPs if the LSP or any of its personnel:

(i) had been convicted of an offence involving psychotropic drugs or other drugs of abuse or counterfeit drugs, or a large quantity of controlled drugs; or

(ii) had had a previous conviction within the last three years;

(b) in all other cases, a written warning would be issued to the LSP.

**Since November 2000 (extracted from the Licensing and Disciplinary Criteria of the Board)**

Against ASPs

A disciplinary inquiry will also be held for first-time convictions involving illegal possession or sale of unregistered medicines. The revised policy is:

(a) a disciplinary inquiry will be held if an ASP or any of its personnel:

- has been convicted of an offence involving psychotropic drugs or sale of cough medicines or zoplicone; or
- has been convicted of illegal possession or sale of unregistered pharmaceutical products; or
- has been convicted of illegal possession for sale or for any purpose of trade or manufacture goods to which a forged trademark is applied; or
- had a previous conviction, the date of offence of which had been within three years of the date of offence of the present conviction.

(b) For other infringement, the proprietor/director and pharmacist of the ASP will be interviewed by the Chief Pharmacist and the Board's Secretary to give them verbal caution in all other cases.

Against LSPs

An LSP will also be removed from the List of LSPs for first-time convictions involving illegal possession or sale of unregistered medicines. The revised policy is:

(a) an LSP will be removed from the List of LSPs if the LSP or any of its personnel:

- has been convicted of an offence involving psychotropic drugs or other drugs of abuse; unregistered pharmaceutical products; or a large quantity of controlled drugs; or
- has been convicted of possession for sale or for any purpose of trade or manufacture goods to which a forged trademark is applied; or
- had a previous conviction within the last three years, the date of offence of which had been within three years of the date of offence of the latter conviction.

(b) in all other cases, a written warning will be issued to the LSP.

Annex 2

**Statement by Chief Pharmacist, Department of Health in response to the letter from Clerk to Public Accounts Committee dated 29.12.2009**

I would first apprise the Public Accounts Committee of the overall environment on Government Expenditure in 1999-2007 as follows –

1. Under an Enhanced Productivity Programme (EPP), government departments were required to reduce, between April 1999 and March 2003, their baseline expenditure by a total of 5%.

2. A Voluntary Retirement Scheme was launched in July 2000.

3. Against a forecast of huge fiscal deficit, the then Financial Secretary announced in February 2003 a target to reduce operating expenditure by $20 billion from 2003-04, to $200 billion by 2006-07 through, inter alia, the following measures :

   - ✓ reducing civil service establishment by 10%
   - ✓ launching a second round of Voluntary Retirement Scheme
   - ✓ freezing civil service recruitment.

4. The civil service recruitment freeze introduced in April 2003 was lifted in April 2007.

5. There were no Resource Allocation Exercises (RAEs) in 1999-2004, except for 2001. The 2000 RAE was restricted to major policy initiatives.

The following suggestions which I made in the past 10 years for tightening up control of importation of unregistered medicines for re-export purposes should be seen against the above background –

1. seeking the agreement of the Department not to reduce the number of staff involved in inspection and prosecution duties when the Government implemented the EPP in 1999-2003. Proposal accepted by Department;

2. excluding the Pharmacist grade, which forms the backbone for undertaking inspection and prosecution duties, from the two rounds of Voluntary Retirement Schemes in 2000 and 2003. Proposal accepted by Department;

3. tightening post-conviction actions against licensed retailers by the Pharmacy and Poisons Board in respect of convictions involving unregistered medicines: instead of a warning, a disciplinary enquiry to be held against convicted authorized sellers of poisons (ASPs), and licence removal against convicted listed sellers of poisons (LSPs). Proposal implemented in November 2000. As a result of this, from 2001 to 2009, 49 ASPs were convicted, in which 22 had suspension of licence, and 50 LSPs were convicted, in which 27 had their licence removed;

4. amending legislation to require importers to keep full transaction records of unregistered medicines imported for the purpose of re-export, to submit copies of the same to the Pharmacy and Poisons Board as and when required, and to make them available for inspection on site as and when required. Proposal agreed by the Pharmacy and Poisons Board and submitted to the then Health, Welfare and Food Bureau in February 2001. (It subsequently transpired that, as per legal advice received from the Department of Justice, amendment of the principal ordinance would be required in addition to amendment of the subsidiary legislation);

5. making submissions to strengthen manpower provision to enhance the control of medicines. Without divulging the details of RAEs, which is an internal process, the manpower provision of the Department of Health (including those for the control of medicines) is set out in the Annual Estimates of the Government.

(A.W.K. Chan)
Chief Pharmacist
Department of Health
22.1.2010

# Report of the

# Review Committee on
# Regulation of Pharmaceutical Products in Hong Kong

**Food and Health Bureau**

**December 2009**

# CONTENT



*Note by Clerk, PAC: ***Chapters 1 to 10 and Annexes A to J not attached.***

# Executive Summary

## INTRODUCTION

In early 2009, a number of incidents concerning pharmaceutical products in Hong Kong had caused public concerns on drug safety. The Food and Health Bureau (FHB) and Department of Health (DH) took immediate measures to address the concerns, including the inspection of all local drug manufacturers. As a longer term measure, it was decided that a comprehensive review on the existing regime for the regulation of pharmaceutical products (western medicines) be conducted.

## SETTING UP OF THE REVIEW COMMITTEE ON THE REGULATION OF PHARMACEUTICAL PRODUCTS IN HONG KONG

2. The Review Committee on the Regulation of Pharmaceutical Products in Hong Kong (Review Committee) chaired by the Permanent Secretary for Health with members from the pharmaceutical sector, medical profession, academia, patient groups and consumer representative was set up on 24 March 2009. In consideration of the wide range and complexity of the issues to be examined, the Review Committee set up two Sub Committees, one on drug manufacturing and another on drug distribution and procurement to examine the various issues in depth. 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 set up to give advice on the microbiological hazards on drug manufacturing. The background of the review, the terms of reference, membership and work of the Review Committee, the two Sub Committees, the Task Force and the Expert Group are set out in Chapter 1 (and Annexes A to C) of this report.

## PRESENT SITUATION

3. The current drug regulatory regime adopts a risk management, dual target and multi-pronged approach backed by the law. The dual targets are the pharmaceutical products and the pharmaceutical trade. Multi-pronged approach embraces legal requirements and administrative measures which provide the framework of the control system, education for the pharmaceutical sector to equip them 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 follow through each point in the production line and the supply chain until the drug reaches its target patients. The framework of the regime is similar to those of many overseas jurisdictions, but the implementation details could differ from one place to another. Chapter 2 of the review report provides an overview of the existing regulatory regime.

## UNDERLYING PRINCIPLES OF THE REGULATORY REGIME

4. The Review Committee agrees that the regulatory regime of the pharmaceutical sector should adhere to the following key principles and objectives:

(a) protecting public health and ensuring patient safety is the top priority;

(b) the regulatory regime should be able to maintain public confidence on the usage of drugs;

(c) the regulatory regime should be able to sustain and improve the standard of the pharmaceutical sector, but at the same time able to identify and address any bad practices;

(d) the regulatory regime should be fair, accountable, consistent and transparent; and

(e) the regulatory regime has to strike a fine balance between effective regulation and the challenges to the trade and the professionals.

5. The Review Committee agrees that while the Government has the responsibility to regulate, the pharmaceutical trade has the responsibility to comply with the prescribed requirements and standards, to enhance governance and the audit process. The pharmacist profession and all healthcare professionals have the responsibility to discharge their duties and uphold their high professional standards.

## FINDINGS AND RECOMMENDATIONS OF THE REVIEW

6. With the above principles in mind, the Review Committee has examined in detail the existing regulatory regime. It considers that the framework and the rationale behind the existing regime is sound and while it should continue to be adopted, the coverage and depth of the regulatory

measures should be enhanced. The Review Committee is, however, mindful of the implementation details and considers that while changes should be made to enhance the effectiveness of the regime, various proposed new measures should have an implementation programme, taking into account the lead time required to acquire resources, train the personnel both within DH and in the trade, set up the system for the stakeholders to follow or adapt, and to take forward the legislative amendments. Nevertheless, proposals which are key to enhance drug safety should be implemented with priority. At the same time, the Review Committee believes that the pharmaceutical sector plays a pivotal role in protecting the integrity of the system by observing self-discipline and upholding the pharmacist professional standards.

7. The Review Committee has made a total of 75 recommendations, covering the following different aspects as summarised in the ensuing paragraphs (and Annexes D and E).

**(a) Regulation of drug manufacturers and Good Manufacturing Practices (GMP) Scheme (Chapter 3)**

(i) **To upgrade the current Hong Kong GMP standard to a higher international standard**: GMP is a quality assurance approach used by the drug manufacturing industry worldwide to ensure that products are consistently produced and controlled throughout the manufacturing process. The spirit of GMP emphasizes that the assessment of good quality should be based on scrutiny of the manufacturing processes and not by testing of the end product alone. Hong Kong is now adopting the GMP standard promulgated by the World Health Organization (WHO) in 1995. The Review Committee recommends that in about two years' time the GMP standard of Hong Kong be first upgraded to the standard promulgated by WHO in 2007, and in about another two years' time it should be upgraded to an even higher standard devised by the Pharmaceutical Inspection Cooperation Scheme, i.e. the PIC/S standard. The PIC/S standard includes a stricter control over the use of active pharmaceutical ingredients for drug manufacturing, more stringent qualification requirements for the position of the authorized person who oversees the entire drug manufacturing process, a more enhanced inspection and licensing arrangement, and a more comprehensive training framework for all levels of personnel involved in the GMP system. This recommendation should be implemented with priority.

(ii) **To introduce microbiological monitoring for non-sterile drugs during the manufacturing process**: In the light of the earlier incident of fungal contamination of drugs, the Review Committee recommends that local manufacturers be required to conduct microbiological tests for non sterile drugs. Drug manufacturers will be required to adopt a new model for microbiological monitoring, including the carrying out of microbiological tests on raw materials, limiting the time whereby the granules can be kept to not more than 48 hours, conducting microbiological tests on finished products and including microbiological testing in the stability studies of all products. If a manufacturer intends to adopt a longer holding time, he must provide the necessary data and evidence supporting the proposed holding time to DH for consideration. This recommendation should be implemented with priority.

(iii) **To tighten up the qualification of the Authorized Person (AP) by increasing the required number of years of industrial experience and imposing requirements on training**: A formal set of criteria regarding the qualifications of the AP will be set, alongside with the introduction of a structured training programme and a mechanism to ensure that APs will take responsibility for the quality, safety and efficacy of their drug products. In the meantime, the position of AP will still be required to be filled by pharmacist with relevant experience. In the long run when a licensing or listing system for APs and additional formal certified GMP training have been developed, consideration will be given to allowing additionally non-pharmacists with the required experience and training to assume the position of AP.

(iv) **To require all companies which undertake repackaging activities, including secondary repackaging in addition to primary repackaging, to have a manufacturing licence**: A new category of repackaging licence will be introduced for such purpose. This recommendation should be implemented with priority.

**(b) Pre-market control of drugs (Chapter 4)**

(i) **To require bioavailability and bioequivalence (BABE) studies for drug registration**: BABE refers to 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. This is particularly important for some drugs, such as antiepileptic drugs, where a reduced or excessive therapeutic effect could be harmful to the patient. The Review Committee recommends that BABE studies be required for drug registration. To allow time for the market to build up its capacity for carrying out the studies, the recommendation will be implemented in phases, starting with drugs where a reduced or excessive therapeutic effect could have undesirable consequences.

(ii) **To Change the term "Poison 毒藥" on drug labels**: The term "poison" in drug labels arouses unnecessary concern of the public regarding the safety of the drug. The Review Committee recommends that alternative terms be devised. One recommendation is to adopt the terms "prescription drugs 處方藥" and "drugs under supervised sale 監售藥". The Pharmacy and Poisons Board should consult the stakeholders on the most appropriate terms.

(iii) **DH to shorten the processing time for drug registration approval**: As a result of manpower constraints, the processing time for approval of registration of drugs, for change of particulars of registered drugs and for clinical trials are quite long. The Review Committee recommends that DH shortens the time by 40% - 50%.

**(c) Regulation of importers/exporters, wholesalers and retailers (Chapter 5)**

(i) **To require wholesalers handling non-poisons to apply for a licence:** At present, wholesalers of drugs which are non-poisons (e.g. vitamins) are not subject to licensing control. The Review Committee considers that patients' health would be affected if these drugs are not handled properly. The Review Committee recommends that DH requires all wholesalers of non-poisons to apply for a licence so that DH could impose licensing requirements on them.

(ii) **To require wholesalers to keep transaction records for Part II Poisons and non-poisons**: At present the law only requires wholesaler to keep transaction records for Part I Poisons. The Review Committee recommends that wholesalers also keep transaction records for all pharmaceutical products, including Part II Poisons and non-poisons. This will ensure that drugs are being

procured through a proper channel and the sources can be traced if problems arise.

(iii) **To introduce a Code of Practice for wholesalers, importers and exporters**: At present there are no guidelines governing the roles and responsibilities of wholesalers, importers and exporters on product quality, as opposed to the GMP compliance for manufacturers. The Review Committee recommends that a Code of Practice be introduced for wholesalers, importers and exporters to follow.

(iv) **To strengthen the control of the import and export of pharmaceutical products:** The Review Committee recommends DH to deploy a designated team to provide advice to the Customs and Excise Department (C&ED) at ports of entry and to undertake surveillance work.

(v) **To strengthen the tracking system for drugs imported for re-export purpose:** The Review Committee recommends DH to set up a record and tracking system so that export licence applicants are required to produce the relevant import licences of the imported drugs to be re-exported. This will enable DH staff to keep track of the amount imported and the amount intended to be exported to prevent illegal diversion of drugs imported for re-export purpose into the local market. In the long run, an electronic record system which is inter-operable with C&ED and the Trade and Industry Department should be a more efficient alternative. In addition, the weekly quota of post-shipment consignment checks of licence by C&ED will be increased, taking into account the workload of C&ED staff.

(vi) **To require retailers handling non-poisons to apply for a licence**: At present, retailers of non-poisons are not required to apply for a licence. Although non-poisons are drugs of lower risk, they will still affect public health if not being handled properly. The Review Committee recommends that retailers selling non-poisons be required to apply for a licence from DH.

(vii) **To require the presence of pharmacists during all business hours of pharmacies**: At present, a registered pharmacist has to be present in an Authorized Sellers of Poisons (ASPs), i.e. pharmacies, for not less than two-third of its opening hours. The Review Committee recommends that in the long run a registered

pharmacist should be present whenever an ASP is open for business. This will improve the professional services provided by pharmacists. To further enhance the role of pharmacists in the control of the storage and supply of drugs at ASPs, apart from the above proposal, heightened enforcement actions should be taken against non-pharmacists who have violated the law or interfered with the duties of pharmacists. The Review Committee noted that this recommendation should take into account the market operating conditions as well as the availability of sufficient pharmacists and cannot be implemented immediately.

(viii) **To include in the law the requirement for retailers to follow their Codes of Practice**: The existing Code of Practice for ASPs, i.e. pharmacies, has no legal status for enforcement, and there is no Code of Practice for Listed Seller of Poisons (LSPs), i.e. medicine companies, to follow with regard to the handling of drugs. The Review Committee recommends that a Code of Practice be devised for LSPs and the law be amended to require that both ASPs and LSPs have to follow their respective Codes of Practice.

(ix) **To empower the Pharmacy and Poisons Board (PPB) to revoke licences of ASPs**: At present the PPB can only stop renewing licences of ASPs at the beginning of each year, but has no authority to revoke the licence during the year. The Review Committee recommends giving such authority to the PPB so that the licence of an ASP can be revoked if it has committed a serious offence.

(x) **To require retailers and doctors to have written records for drug orders**: This is to ensure that there is proper record and checking mechanism to prevent errors during delivery of drugs which is necessary to protect the safety of patients. The Review Committee notes that the trade would need time to work out a system with the suppliers. In the long run, electronic record should be a more efficient alternative. The Review Committee also notes that the written record requirement is already recommended in the "Good Dispensing Practice Manual" issued by the Hong Kong Medical Association and the Hong Kong Medical Council has advised doctors to observe the Manual. The Hong Kong Doctors Union objects to the mandatory requirement of written order of drugs.

**(d) Procurement and supply of pharmaceutical products in the public and private medical sectors (Chapter 6)**

(i) **The Hospital Authority (HA) and DH to require suppliers to provide detailed information on the delivery documentation:** HA and DH will require supplier to provide information such as pack size and registration number in the delivery documents to enable more effective checking and verification of drugs received. This recommendation should be implemented with priority.

(ii) **HA and DH to check the quality of drugs**: Microbiological and chemical testings will be conducted to ensure drug quality. This recommendation should be implemented with priority.

(iii) **DH to encourage the private medical sector to follow the proposed set of guiding principles on drug handling**: DH will issue a set of guiding principles for all private hospitals. The principles include the selection, procurement, delivery and receipt, storage and repacking of drugs, staff training and auditing. This recommendation should be implemented with priority.

**(e) Post-market control of drugs and Pharmacovigilance (Chapter 7)**

(i) **DH to continue the extended coverage for the surveillance of high risk products in the market**: DH has increased the number of drug samples collected in the market for testing to over 2 000 in recent years. The Review Committee recommends DH to continue with such rigorous surveillance and the existing practice of reporting anomalies to the public. This recommendation should be implemented with priority.

(ii) **DH to enhance Pharmacovigilance activities**: Pharmacovigilance is the detection, assessment, understanding and prevention of adverse effects of drugs. DH will promote these activities through education, training and promotion among healthcare professionals and the trade and to foster a culture of awareness of pharmacovigilance.

**(f) Risk communication, education and training (Chapter 8)**

(i) **DH to set up a dedicated team for education and training**: At present there is no coordination amongst various organizations which provide public education programmes on drug safety. The

Review Committee recommends DH to set up a dedicated team to coordinate the efforts of various parties, to draw up guidelines on risk communication and to perform risk assessment in response to incidents and to recommend risk communication actions. This recommendation should be implemented with priority.

(ii) **DH to provide more information on drugs to the public**: Drug information in the existing DH's electronic compendium of pharmaceutical products are not comprehensive and user friendly enough. The Review Committee recommends that the content of the compendium be enhanced. The Review Committee also recommends the setting up of a designated website to promote drug safety. This recommendation should be implemented with priority.

**(g) Penalty review (Chapter 9)**

(i) **To strengthen the penalty on manufacturers**: The Review Committee recommends authorizing the Manufacturing Licensing Committee of the Pharmacy and Poisons Board to remove the authorized person when he breaches his duties and to stop the production of the manufacturer when the authorized person has been removed.

(ii) **To require the convicted person to bear the costs for analyzing exhibits in court cases**: The cost for analyzing exhibits in court cases could be substantial. The Review Committee recommends that the law be amended to require the convicted person to bear such costs in order to increase the deterrent effect.

(iii) **To provide the Court with more background information in prosecution cases:** DH should present more information to the Court to reflect the seriousness of the offence concerned for the Court to consider the penalty proportionate to the seriousness of the offence.

8. Chapter 10 of this report provides a general assessment on the resources implications of implementing the recommendations, while Chapter 11 summarizes the recommendations and concludes the work of the Review Committee. A glossary of terms is at *Annex F* for reference.

## WAY FORWARD

9. The Review Committee has completed its task by giving recommendations on the measures to improve the existing regime. The Government will take follow up actions to implement these measures. The Food and Health Bureau will oversee the policy issues, and together with the Department of Health, will take forward the necessary legislative amendments, address the resource implications and requirements involved. The Department of Health and Hospital Authority will also be responsible for the implementation of the recommendations, consulting the stakeholders in the process. The implementation programme of the various recommendations is set out at *Annex D*. Some of the recommendations will be implemented subject to the passing of the relevant legislative amendments and may require a longer timeframe for implementation. A list of such recommendations is at *Annex E*.

10. Whilst the recommendations will be implemented in different phases, the Review Committee also recommends that a dedicated office on drugs should be set up to strengthen the regulatory role of the Government in enhancing drug safety in Hong Kong as a matter of priority . The office will plan and direct the implementation of measures relating to drug safety. DH will work closely with the pharmaceutical trade and all stakeholders to plan for the setting up of the office. In the long run, consideration will be given to expanding the office to be a "Centre for Drug Safety".

11. The Review Committee also notes that the Pharmacy and the Poisons Ordinance needs to be kept under regular review taking into account the changes in the operating environment of the pharmaceutical trade.

12. The Review Committee Chairman expresses her gratitude to all its Members, the pharmaceutical and medical sectors, academia, patient groups and consumer representative for their invaluable advice and unfailing support during the whole course of the review. The recommendations of the Review Committee will be implemented through the tripartite collaboration among the regulatory authority, the trade and consumers. All parties would need to maintain their heightened vigilance against any mal-practices. We believe that the key to the success in raising the standard of the pharmaceutical sector in Hong Kong lies in an effective regulatory regime, the commitment and determination of the professionals to practise to their highest standards and the trade to perform responsibly.

## IN MEMORIAM

13. The Review Committee is very saddened that one of its Members, Ms Sandra CHOW, Chairperson of Care for your Health - Cardiac Patients Mutual Support Association, passed away in late-December 2009 just before the completion of this review. Ms CHOW had participated actively in all meetings of the Review Committee as well as its subcommittees and had contributed many useful and constructive ideas from the patients' perspective on a wide range of topics. The Chairman and all Members of the Review Committee would like to express their deepest condolences to Ms CHOW's family.

# CHAPTER 11 SUMMARY OF RECOMMENDATIONS

## Overview

11.1 This chapter gives a summary on all the recommendations and concludes the work of the Review Committee.

## Summary of Recommendations

11.2 The Review Committee has made a total of 75 recommendations as follows. Recommendations which can be implemented with existing resources are marked with an "*" while recommendations which will be implemented when new resources are available are marked with an "#".

*Regulation of Drug Manufacturers*

**Recommendation 1#** – to upgrade Hong Kong's current GMP licensing standards by a phased approach to PIC/S standards over a period of fours years. (paragraphs 3.15 – 3.16 above)

**Recommendation 2#** – to require imported drugs to comply with the same standards once local drugs attained the PIC/S standards. (paragraph 3.17 above)

**Recommendation 3#** – to strengthen the control of the use of Active Pharmaceutical Ingredients (APIs) and contract laboratories by local manufacturers. (paragraph 3.18 above)

**Recommendation 4*** – to strengthen the experience requirement for existing APs from at least one year of relevant working experience to at least three years; and for the heads of production and quality control from at least one year to at least two years for pharmacy degree holders and from at least two years to at least three years for holders of higher diploma in pharmacy-related subjects. (paragraph 3.19 above)

**Recommendation 5#** – to draw up a set of qualification requirements of Authorized Persons (APs), to establish a licensing or listing scheme and to liaise with the universities for offering a structured training programme for APs. (paragraph 3.20 above)

**Recommendation 6#** – to empower the Pharmacy and Poisons Board to maintain an AP register and remove any AP from the register should he be found incompetent to perform the AP role. (paragraph 3.22 above)

**Recommendation 7*** – to increase the number of inspections to local manufacturers. While most of the inspections to manufacturing premises should remain announced, some unannounced inspections should be introduced. Further, one of the two inspectors in the inspection team should be retained for subsequent inspections to facilitate effective follow-up on irregularities identified. (paragraph 3.25 above)

**Recommendation 8#** – to set up a multi-disciplinary GMP inspection team with professionals of other related disciplines like biochemists, chemists, engineers, microbiologists, etc. for effective auditing of manufacturers with diversified production environment. (paragraph 3.27 above)

**Recommendation 9#** – to develop structured, practical and continuous training programmes for all levels of players in the GMP system including DH inspectors, APs, production and quality control heads, and other workers. (paragraph 3.28 above)

**Recommendation 10*** – to state in the licensing conditions that local manufacturers should either (a) appoint the AP as a board member; or (b) invite the AP to attend board meetings and allow the AP to speak and have his remarks put on record where safety, efficacy and quality issues of products are concerned. This recommendation should be put on trial for two years and then reviewed. (paragraphs 3.29 – 3.32 above)

**Recommendation 11#** – to introduce a code of practice to govern the conducts of the manufacturers and the APs. (paragraph 3.33 above)

**Recommendation 12*** – to require all local manufacturers to adopt the enhanced microbiological monitoring model covering raw materials, granules, finished products and stability studies. (paragraphs 3.34 – 3.39 above)

*Pre-market Control of Drugs*

**Recommendation 13#** – to require BABE studies as registration requirement for pharmaceutical products to enhance quality of generic drugs. The implementation should be by phases starting in April 2010. It will begin with antiepileptic drugs, which have a narrow therapeutic index where a comparatively small difference in the absorption of the drug by the human body may lead to undesirable consequences. (paragraph 4.14 above)

**Recommendation 14*** – to replace the term "Poison 毒藥", as required to be labelled on pharmaceutical products classified as poisons, with other terms to alleviate the unnecessary concern of consumers that the products might be harmful and unsuitable for use or consumption. (paragraph 4.15 above)

**Recommendation 15*** – to delete the phrase "to be marketed for use within Hong Kong" on the certificate of registration of pharmaceutical products. (paragraph 4.16 above)

**Recommendation 16*** – to extend the validity of clinical trial certificate from not more than two years to not more than five years. (paragraph 4.17 above)

**Recommendation 17#** – to shorten the time-frame for processing applications for registration of pharmaceutical products, change of particulars of registered products and clinical trials by 40% - 50%. (paragraph 4.18 above)

*Regulation of Importers/Exporters and Wholesalers*

**Recommendation 18#** – to require all wholesalers of non-poisons to be subject to inspection and licensing control. (paragraphs 5.17 – 5.18 above)

**Recommendation 19#** – to require all wholesalers to keep transactions records of all pharmaceutical products, including Part II poisons and non-poisons in the same manner as for Part I poisons, and to require wholesalers to keep samples of each batch of drugs handled to facilitate investigation when needed. (paragraphs 5.19 – 5.20 above)

**Recommendation 20*** – to require both primary and secondary packaging be carried out by a licensed manufacturer. (paragraphs 5.21 – 5.22 above)

**Recommendation 21*** – to introduce a code of practice for importers/exporters and wholesalers detailing their roles and responsibilities, including the requirement of batch release certificate, the reporting of adverse drug reactions, proper storage and transportation of drugs, etc. (paragraphs 5.23 – 5.24 above)

**Recommendation 22#** – to strengthen the monitoring of importers/exporters and wholesalers by means of more frequent and more detailed inspections, especially after the introduction of a code of practice. (paragraphs 5.25 – 5.26 above)

**Recommendation 23#** – to set up a dedicated team of pharmacist inspectors to advise C&ED staff on pharmaceutical imports at various ports of entry. (paragraphs 5.27 – 5.28 above)

**Recommendation 24#** – to set up a record and tracking system by requiring EL applicants to produce the ILs of the imported drugs to be re-exported. (paragraph 5.29 above)

**Recommendation 25#** – to prescribe in the licensing conditions for ILs for the products for re-export that the importer should not sell unregistered imported drugs in Hong Kong and must re-export the products within a specified period of time, say one year. (paragraph 5.30 above)

**Recommendation 26#** – to conduct a joint review with C&ED to determine a new weekly quota for post-shipment consignment checks of licences which should be a statistically significant sample size of the ILs and ELs population. (paragraph 5.31 above)

**Recommendation 27#** – to require exporters who chose to export products by mail to clear their products at designated post offices. DH should include the requirement in the ELs and discuss with C&ED for the introduction of a daily quota on outgoing mail parcels of drugs for verification of content and endorsement by C&ED. (paragraph 5.32 above)

**Recommendation 28#** – to develop an electronic record system among DH, C&ED and TID to facilitate the tracking of imported and exported drugs. (paragraph 5.33 above)

*Regulation of Retailers*

**Recommendation 29#** – to require all retailers of non-poisons to be subject to licensing and inspection control. (paragraphs 5.49 – 5.50 above)

**Recommendation 30#** – in the longer term after taking into account the market operating conditions and the availability of sufficient pharmacists, to require the presence of a registered pharmacist whenever an ASP is open for business. Heightened enforcement actions should be taken against those non-pharmacists who violate and interrupt the pharmacists' performance of their duties at ASPs. (paragraphs 5.51 – 5.54 above)

**Recommendation 31*** – to require all Part I Poisons be stored in locked receptacle in the premises of an ASP and that only the pharmacist should hold the key to the locked receptacle. (paragraphs 5.55 – 5.56 above)

**Recommendation 32*** – to add a provision in the Pharmacy and Poisons Ordinance for the issuance and revision of the code of practice for ASPs in order to give a legal status to the code to enhance monitoring on the operation of ASPs; and to introduce a code of practice for LSPs which should enjoy the same legal status as the code for ASPs. (paragraphs 5.57 – 5.58 above)

**Recommendation 33*** – to give the Pharmacy and Poisons Board the authority to revoke the licence of an ASP at any time after the ASP has been convicted of serious drug offence. (paragraphs 5.59 – 5.60 above)

**Recommendation 34*** – to tighten the licensing conditions for the refusal or renewal of ASP or LSP applications. DH should evaluate what type of drug offences should be included based on their public health impact. (paragraphs 5.61 – 5.62 above)

**Recommendation 35#** – to strengthen the monitoring of ASPs and LSPs by means of more frequent and more detailed inspections. (paragraphs 5.63 – 5.64 above)

**Recommendation 36*** – to require ASPs and LSPs to purchase drugs from licensed traders only. (paragraphs 5.65 – 5.66 above)

**Recommendation 37*** – to require that all orders for drugs to have written records. (paragraphs 5.67 – 5.73 above)

**Recommendation 38*** – to require ASPs to sell pharmaceutical products in their original packing, save in the case of a doctor prescription drug which is required by law to be dispensed in exact quantity in accordance with the prescription and in the case of pharmacist dispensing drugs to patients according to their need with proper labelling. (paragraphs 5.74 – 5.75 above)

**Recommendation 39*** – to require ASPs and LSPs to keep all the supporting documents including drug orders and sales invoices related to every purchase of all pharmaceutical products, and the documents should be kept as long as the expiry date of the pharmaceutical product concerned for DH's inspection if necessary. (paragraphs 5.76 – 5.77 above)

*Regulation of Drug Procurement*

**Recommendation 40#** – both DH and HA to conduct post-delivery surveillance including microbiological and chemical testing to ensure drug quality. (paragraph 6.14(a) above)

**Recommendation 41*** – both DH and HA to require the suppliers to provide additional information, such as pack size and registration number, etc. in the delivery documents to enable more effective physical checking and verification if drugs received are legally conforming. (paragraph 6.14(b) above)

**Recommendation 42#** – both DH and HA to provide additional training to staff and monitor the workflow in the repacking activities in drug dispensing to minimize errors. (paragraph 6.14(c) above)

**Recommendation 43*** – to impose a new requirement on suppliers to keep samples of each batch of drugs that are still within the expiration period to facilitate investigation when needed. (paragraph 6.14(d) above)

**Recommendation 44#** – to upgrade DH's central inventory monitoring computer system to enhance the traceability of drugs. (paragraph 6.14(e) above)

**Recommendation 45#** – DH to enrich the database of registered pharmaceutical products so as to provide more detailed information to the public on registration details of products, e.g. pack-size, labelling, legal classification, etc. (paragraph 6.14(f) above)

**Recommendation 46*** – HA to require suppliers to provide evidence that their products are either registered or are exempted from registration under the law. (paragraph 6.14(g) above)

**Recommendation 47*** – HA to require suppliers to provide microbiological test results for high risk drug items and batch release certificates on all drugs supplied to HA to ensure safety and quality. (paragraph 6.14(h) above)

**Recommendation 48*** – HA to use multiple sources for supply of high risk products with high usage volume. (paragraph 6.14(i) above)

**Recommendation 49#** – HA to establish a Drug Quality Assurance Office to enhance quality monitoring of products, performance management of manufacturers and suppliers and quality incident management as well as to monitor the implementation of all improvement initiatives. (paragraph 6.14(j) above)

**Recommendation 50#** – HA to enhance the current electronic system, such as exploring the use of RFID, bar coding, wireless data transmission, etc. to enable product traceability and effective stores management. (paragraph 6.14(k) above)

**Recommendation 51*** – HA to require suppliers to provide drugs in suitable pack sizes as far as possible to reduce the need for repacking. (paragraph 6.14(l) above)

**Recommendation 52*** – DH to issue a set of guiding principles on drug procurement for the private medical sector and encourage private hospitals, MCOs and private medical practitioners in solo or joint practices to follow this set of guiding principles as far as practicable. (paragraphs 6.26 – 6.27 above)

**Recommendation 53*** – DH to encourage private hospitals to develop an automated inventory management system and bar-coding system for pharmaceutical products. (paragraphs 6.28 – 6.29 above)

*Pharmacovigilance*

**Recommendation 54*** – to establish a pharmacovigilance advisory body to review DH assessments of the ADR reports received, advise DH on action on specific cases, serve as an editorial advisory board of the pharmacovigilance bulletin and assist DH in the promotion of pharmacovigilance activities. (paragraph 7.16 above)

**Recommendation 55#** – DH to set up a dedicated team to promote pharmacovigilance work among professionals, education institutions and the industry; handle ADR reports received; disseminate information; and support the pharmacovigilance advisory body. (paragraph 7.17 above)

**Recommendation 56*** – DH to publish a regular pharmacovigilance bulletin for distribution to all doctors, dentists and pharmacists, and a user-friendly version of the bulletin for reference of the general public. (paragraph 7.18 above)

**Recommendation 57#** – DH to include an ADR report form in mails to doctors and pharmacists, enhance DH website such that doctors and pharmacists could subscribe and receive emails from DH on ADR as soon as they become known, encourage the use of electronic reporting of ADRs, and develop additional electronic interface for dentists and pharmacists to facilitate ADR reporting. (paragraph 7.19 above)

**Recommendation 58#** – DH to publish guidelines for the drug industry on their responsibilities to report ADRs, to educate and encourage them to report ADRs and to develop a culture of awareness of pharmacovigilance. (paragraph 7.20 above)

**Recommendation 59*** – to require the drug industry to report any actions taken by overseas drug regulatory authorities on any drugs as a consequence of safety issues and require manufacturers to inform DH if they have committed to the request of European Union or United States to develop an EU Risk Management Plans (RMP) or US Risk Evaluation and Mitigation Strategies (REM) as a condition for approving a new drug. (paragraph 7.21 above)

**Recommendation 60*** – DH to review ADR reports within three working days. (paragraph 7.22 above)

**Recommendation 61*** – DH to establish liaison with overseas health authorities for exchange of ADR information as well as providing training on pharmacovigilance to staff. (paragraph 7.23 above)

**Recommendation 62#** – DH to review the progress and effectiveness of the development and implementation of the improved pharmacovigilance measures in two years' time. (paragraph 7.24 above)

**Recommendation 63#** – DH to continue the heightened surveillance against high risk products sold in the market and set up a dedicated team of pharmacists to handle increased sampling of high risk products. (paragraph 7.25 above)

**Recommendation 64*** – to adopt a risk-based approach in drug recall and public communication. Specifically DH should revise the recall guidelines to include the different stages of recall procedures, the classification of the recall, the level of the recall, the strategy of the recall including the dissemination of information to the public, the responsibilities of the trade including refund, and the monitoring of all follow up actions, including the effectiveness of the recall. (paragraphs 7.26 – 7.27 above)

**Recommendation 65*** – DH to inform the Consumer Council on every drug recall incident at consumer level to widen the dissemination network of the drug recall message. (paragraph 7.28 above)

**Recommendation 66*** – DH to add a refund mechanism in the recall guidelines requiring manufacturers and wholesalers to provide refund details to consumers at retail level in the event of drug recall. (paragraphs 7.29 – 7.30 above)

*Risk Communication*

**Recommendation 67#** – to set up a dedicated, multi-disciplinary team to oversee education and training. The team should collaborate with and co-ordinate efforts of the academia, Consumer Council and relevant professional

bodies in the provision of education and training programmes on drug safety. (paragraphs 8.12 – 8.13 above)

**Recommendation 68#** – to continue organizing seminars with additional focus on quality control for the management at different levels of the drug supply chain as well as front-line staff. (paragraphs 8.14 – 8.15 above)

**Recommendation 69#** – to enhance the content of "Compendium of Pharmaceutical Products" on DH website to provide more information about each registered drug. (paragraphs 8.16 – 8.17 above)

**Recommendation 70#** – to set up a designated website on drug safety to provide a better platform for information dissemination and exchange. (paragraphs 8.18 – 8.19 above)

**Recommendation 71*** – to establish a working group to work out the prototype of the enhanced website and its contents. (paragraph 8.19 above)

**Recommendation 72#** – to require that more information on drugs and patient-oriented advice be provided along with drugs dispensed to patients at hospitals or clinics. (paragraphs 8.20 – 8.21 above)

*Penalty System*

**Recommendation 73*** – to include more aggravating factors in the facts of the case submitted to the Court to reflect the seriousness of the offence concerned for the Court to impose an appropriate sentence. (paragraph 9.11(a) above)

**Recommendation 74*** – to amend the Pharmacy and Poisons Ordinance to include provision for the Court to order the convicted person to pay the analytical costs incurred by the Government to increase the deterrent effect. (paragraph 9.11 (c) above)

*Manpower Requirements*

**Recommendation 75#** – to expand DH's Pharmaceutical Service into a dedicated office on drugs to strengthen DH's regulatory role in enhancing drug safety. In the long run, consideration will be given to expanding the office to be a "Centre for Drug Safety". (paragraphs 10.5 – 10.11 above)

**Way Forward**

11.3 The Review Committee has now completed its task. The Review Committee is pleased that the Government has accepted all its recommendations. In particular, the establishment of a dedicated office on drugs and the raising of Hong Kong's GMP licensing standards to PIC/S standards will become major milestones in the enhancement of Hong Kong's drug safety standard.

11.4 The next step is for the Government to join hands with the pharmaceutical sector in implementing the recommendations. The Food and Health Bureau will oversee the policy issues, introduce the necessary legislative amendments and seek the required resources, while DH, HA and the pharmaceutical sector will be responsible for implementation of the recommendations. The Review Committee would like to appeal to the pharmaceutical sector that it is their primary responsibility to practise to their highest professional standards and strive for continuous service improvement. With the joint efforts of all parties, the Review Committee is confident that the standards of the pharmaceutical industry in Hong Kong will be enhanced and public confidence on the use of drugs will be raised.

11.5 The Chairman of the Review Committee would like to thank all the members of the Committee, the pharmaceutical sector, the medical sector, patient groups and the consumer representative for their contributions to the deliberations of the Review Committee. Members have been most generous with their time and they contributed constructively to all discussions and debates at the meetings in this comprehensive review resulting in a total of 75 recommendations. The Food and Health Bureau and the Department of Health look forward to working with all stakeholders to implement these recommendations under the same spirit of cooperation.

Review Committee on
Regulation of Pharmaceutical Products in Hong Kong
Food and Health Bureau
December 2009