

Table 6 Statistics on Complaints against Licensed Chinese Medicines Traders (CMT) (as at 31 December 2012)

Table 6(1) Classification of CMT Against Which Complaints Were Received

Classification of CMT	No. of complaints
1. Retailers in Chinese Herbal Medicines (CHM)	67
2. Wholesalers in CHM	8
3. Wholesalers in Proprietary Chinese Medicines (pCm)	47
4. Manufacturer in pCm	19
Total	141

Table 6(2) Nature of Complaints Received

Explanatory Notes:

(A) Retailers in CHM

Personnel:	Persons (including responsible persons, dispensers and sales persons) engaged in this trade should possess the basic knowledge relevant to their duties and work conscientiously, under proper medicine shop management, to safeguard public health
Premises:	The layout of the business premises should correspond to the nature and scale of the retail business in CHM, including the business area, drawers for processed herbal medicines and store-room
Scope of Business:	The scope of business includes the dispensing and sale of processed herbal medicines (such as verification of prescriptions, preparation, cross-checking, packaging and dispatching, and decoction of processed herbal medicines for customers), sale of single or multiple processed herbal medicines, purchase of processed herbal medicines, inspection, acceptance as well as the storage of processed herbal medicines and labelling; or may process herbal medicines according to business needs, prepare or compound preparations for individual patients according to prescriptions given by Chinese medicine practitioners and dispense single Chinese medicine granules for prescription
Keeping of Records:	The retailer of CHM should keep the transaction documents and dispensing records of Schedule 1 medicines of the Chinese Medicine Ordinance

(B) Wholesalers in CHM

Personnel:	Persons engaged in this trade should possess the basic knowledge relevant to their duties and work conscientiously, under proper business management, to safeguard public health
Premises:	The layout of the business premises should correspond to the nature and scale of the wholesale business in CHM, including the business area and warehouse
Scope of Business:	The scope of business includes the purchase, inspection, acceptance, storage, sale, distribution and transportation of CHM/processed herbal medicines, and labeling; or the process of herbal medicines according to business needs, and sell single Chinese medicine granules for prescription
Complaint of CHM/ Processed Herbal Medicines and Recall System :	The wholesaler of CHM should set up and maintain a system of complaint and recall to enable the rapid and, so far as practicable, complete recall of any CHM/processed herbal medicine sold or distributed, in the event of the medicine being found to be dangerous, injurious to health, or unfit for human consumption
Keeping of Records:	The wholesaler of CHM should keep the transaction documents as well as purchase and sales records of Schedule 1 herbal medicines of the Chinese Medicine Ordinance

(C) Wholesalers in pCm

Personnel:	Persons engaged in this trade should possess the basic knowledge relevant to their duties and work conscientiously, under proper business management, to safeguard public health
Premises:	The wholesaler of pCm should provide suitable premises for the wholesale business in pCm including the business area and warehouse
Scope of Business:	The scope of business includes import and export, or sale of pCm in Hong Kong, or both activities. All pCm should be registered before they can be sold or distributed in Hong Kong. The scope of business includes purchase, inspection, acceptance, storage, sale or distribution and transportation of pCm, labelling and package insert
Complaint of pCm and Recall System :	The wholesaler of pCm should set up and maintain a system of complaint and recall to enable the rapid and, so far as practicable, complete recall of any pCm sold or distributed, in the event of the medicine being found to be dangerous, injurious to health, or unfit for human consumption. They have the responsibility to collect information on all adverse reactions related to their pCm, in the course of processing complaints about such products or through other channels and should communicate such information to the Medicines Board as soon as possible
Keeping of Transaction Documents:	The wholesaler of pCm should keep the transaction documents of the pCm to enable the tracing of the source and distribution channels of pCm suspected to have problems whenever necessary

(D) Manufacturer in pCm

Personnel:	Persons engaged in this trade should possess the knowledge relevant to their duties, and should work conscientiously under proper factory management. This will ensure the manufacture of pCm of good quality, and therefore safeguard public health
Factory:	The manufacturer of pCm should provide suitable premises for the manufacture, examination and storage of pCm/intermediate products
Fittings & Equipment:	The manufacturer of pCm should provide suitable fittings and equipment. Their design, model and installation should conform with the requirements of the manufacturing process. Such fittings and equipment should be easy to operate, clean and maintain
Scope of Business:	The manufacturer of pCm should maintain stringent manufacturing process and management of pCm / intermediate products. The manufacture and management of pCm includes purchase, inspection, acceptance, storage and dispatch of ingredients; production, packing, quality control, storage, sale, and distribution and transportation of pCm; or/and generation, quality control, storage, sale, distribution and transportation of intermediate products
Complaint of pCm/ Intermediate Products and Recall System :	The manufacturer of pCm should set up and maintain a system of complaint and recall to enable the rapid and, so far as practicable, complete recall of any pCm/intermediate product sold or distributed, in the event of the medicine/product being found to be dangerous, injurious to health, or unfit for human consumption. They have the responsibility to collect information on all adverse reactions related to their pCm, in the course of processing complaints about such products or through other channels and should communicate such information to the Medicines Board as soon as possible
Keeping of Records:	The manufacturer of pCm should make proper records and keep relevant documents of purchasing ingredients, operation of manufacturing process, and transaction of pCm/intermediate products

Statistics on Complaints against Licensed Chinese Medicines Traders (CMT):

(A) Retailers in CHM

- (i) 18 complaints involved Personnel. Among of them, 4 complaints also involved the conduct of Chinese medicine practitioners, which have been handled by the Chinese Medicine Practitioners Board.
- (ii) 1 complaint involved Premises.
- (iii) 24 complaints involved Scope of Business. Among of them, 2 complaints also involved the conduct of Chinese medicine practitioners, which have been handled by the Chinese Medicine Practitioners Board.

(B) Wholesalers in CHM

- (i) 3 complaints involved Personnel
- (ii) 2 complaints involved Scope of Business

(C) Wholesalers in pCm

- (i) 23 complaints involved Personnel

- (ii) 2 complaints involved Scope of Business. Among of them, 1 case also involved the conduct of Chinese medicine practitioners, which have been handled by the Chinese Medicine Practitioners Board.

(D) Manufacturer in pCm

- (i) 13 complaints involved Personnel. Allegations against four traders including personnel, factory, conviction of offence(s) punishable with imprisonment and others aspects such as fittings and equipment, scope of business, keeping of records, purchase of ingredients and recall system, etc. As the allegations were mainly against the responsible persons/personnel who did not possess adequate knowledge of pCm and management of the factory, the complaints were classified under “Personnel” .
- (ii) 1 case involved Scope of Business.

(E) CMT convicted of offence(s) punishable with imprisonment has 54 complaints. Among of them, 6 complaints also involved the conduct of Chinese medicine practitioners, which have been handled by the Chinese Medicine Practitioners Board.

The total of number of complaints received is 141 complaints. Among of them, 13 complaints also involved the conduct of Chinese medicine practitioners, which have been handled by the Chinese Medicine Practitioners Board.

Table 6(3) Cases Considered by the Medicines Board and its Decisions

(A) Retailers in CHM

- i. Personnel (total 11 cases)
- a. Allegation(s) substantiated/ Partially substantiated:
- 1case :Temporarily Suspend Licence
 - 1case: Issue Warning
 - 1case: Temporarily Suspend Licence & Vary Licensing Conditions/Restrictions
- b. Allegation(s) not substantiated:
- 1case: Issue Letter of Advice
 - 2 cases: Issue Advisory Letter
 - 5 cases: No Follow-up Action
- ii. Scope of Business (total 17 cases)
- a. Allegation(s) substantiated/ Partially substantiated:
- 4 cases: Issue Warning
 - 2 cases: The Regulatory Committee of Chinese Medicines Traders (CMRC) Issuing Letter of Advice
 - 2 cases: Issue Warning & Vary Licensing Conditions/Restrictions
 - 3 cases: Temporarily Suspend Licence & Vary Licensing Conditions/Restrictions
- b. Allegation(s) not substantiated:
- 2 cases: CMRC Issuing Letter of Advice
 - 1case: Issue Advisory Letter
 - 3 cases: No Follow-up Action

(B) Wholesalers in CHM

- (i) Personnel (total 2 cases)
 - a. Allegation(s) substantiated/ Partially substantiated:
 - 1 case: Temporarily Suspend Licence
 - b. Allegation(s) not substantiated:
 - 1 case: No Follow-up Action
- (ii) Scope of Business (total 2 cases)
 - a. Allegation(s) substantiated/ Partially substantiated:
 - 1 case: Issue Warning
 - 1 case: The Regulatory Committee of Chinese Medicines Traders (CMRC) Issuing Letter of Advice

(C) Wholesalers in pCm

- (i) Personnel (total 18 cases)
 - a. Allegation(s) substantiated/ Partially substantiated:
 - 1 cases: Temporarily Suspend Licence
 - 12 cases: Issue Warning
 - 1 case: Temporarily Suspend Licence & issue warning
 - b. Allegation(s) not substantiated:
 - 4 cases: No Follow-up Action
- (ii) Scope of Business (total 1 case)
 - a. Allegation(s) not substantiated:
 - 1 case: CMRC Issuing Letter of Advice

(D) Manufacturer in pCm

- (i) Personnel (total 9 cases)
 - a. Allegation(s) substantiated/ Partially substantiated:
 - 1 case: Revoke Licence
 - 2 cases: Temporarily Suspend Licence
 - 4 cases: Issue Warning
 - 1 case: Issue Warning & Vary Licensing Conditions/Restrictions
 - 1 case: Vary Licensing Conditions/Restrictions and CMRC Issuing Letter of Advice
- (ii) Scope of Business (total 1 case)
 - a. Allegation(s) substantiated/ Partially substantiated:
 - 1 case: Issue Warning

(E) CMT convicted of offence(s) punishable with imprisonment (total 30 cases)

- a. Allegation(s) substantiated/ Partially substantiated:
 - 4 cases: Revoke Licence
 - 13 cases: Temporarily Suspend Licence
 - 1 case: Vary Licensing Conditions/Restrictions
 - 10 cases: Issue Warning
 - 2 cases: Temporarily Suspend Licence & issue warning

The total cases considered by the Medicines Board and its decisions: (total 91 cases)

- a. Allegation(s) substantiated/ Partially substantiated:
 - 5 cases: Revoke Licence
 - 18 cases: Temporarily Suspend Licence
 - 1 case: Vary Licensing Conditions/Restrictions
 - 33 cases: Issue Warning
 - 3 cases :The Regulatory Committee of Chinese Medicines Traders (CMRC) Issuing Letter of

Advice

- 3 cases: Issue Warning & Vary Licensing Conditions/Restrictions
- 3 cases: Temporarily Suspend Licence & issue warning
- 4 cases: Temporarily Suspend Licence & Vary Licensing Conditions/Restrictions
- 1 case: Issue Letter of Advice
- 1 case : Vary Licensing Conditions/Restrictions and CMRC Issuing Letter of Advice

b. Allegation(s) not substantiated:

- 3 cases: CMRC Issuing Letter of Advice
- 3 cases: Issue Advisory Letter
- 13 cases: No Follow-up Action