

Table 6

Statistics on Complaints against Licensed Chinese Medicines Traders (CMT) (as at 31 December 2017)

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

Classification of CMT	No. of complaints
1. Retailers in CHM	97
2. Wholesalers in CHM	16
3. Wholesalers in pCm	79
4. Manufacturer in pCm	45
Total	237

Table 6(2) Nature of Complaints Received

Nature (See Explanatory Notes)	No. of Cases (Note 1)
(A) Retailers in CHM	
(i) Personnel	24 (4)
(ii) Premises	1
(iii) Scope of Business	27 (2)
(iv) Keeping of Records	
(B) Wholesalers in CHM	
(i) Personnel	5
(ii) Premises	
(iii) Scope of Business	2
(iv) Complaint of CHM/Processed Herbal Medicines and Recall System	
(v) Keeping of Records	
(C) Wholesalers in pCm	
(i) Personnel	38
(ii) Premises	
(iii) Scope of Business	3 (1)
(iv) Complaint of pCm and Recall System	
(v) Keeping of Transaction Documents	
(D) Manufacturer in pCm	
(i) Personnel	24 (Note 2)
(ii) Factory	
(iii) Fittings & Equipment	
(iv) Scope of Business	7
(v) Complaint of pCm/Intermediate Products and Recall System	
(vi) Keeping of Records	
(E) CMT convicted of offence(s) punishable with imprisonment	106 (6)
Total	237 (13)

Note 1 : Figure in bracket representing number of cases which also involved the conduct of CMPs and have been handled by the Chinese Medicine Practitioners Board.

Note 2 : 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 cases were classified under 'Personnel'.

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

Nature (See Explanatory Notes)	Decision of the Medicines Board														Total		
	Allegation Substantiated/Partially Substantiated											Allegation Not Substantiated					
	Revoke Licence	Temporarily Suspend Licence	Vary Licensing Conditions/Restriction	Issue Warning	The Regulatory Committee of Chinese Medicines Traders (CMRC) Issuing Letter of Advice	Others						CMRC Issuing Letter of Advice	Issue Advisory Letter	No Follow-up Action			
						Issue Warning & Vary Licensing Conditions/Restrictions	Temporarily Suspend Licence & Issue Warning	Temporarily Suspend Licence & Vary Licensing Conditions/Restrictions	Issue Letter of Advice	Vary Licensing Conditions/Restrictions and CMRC Issuing Letter of Advice	Temporarily Suspend Licence, Vary Licensing Conditions/Restrictions & Issue Warning					Issue Warning and CMRC Issuing Letter of Advice	
(A) Retailers in CHM																	
(i) Personnel		1		3	1				1	1					2	6	15
(ii) Premises																	
(iii) Scope of Business				6	2	2		3						2	1	3	19
(iv) Keeping of Records																	
(B) Wholesalers in CHM																	
(i) Personnel		1		2										1		1	5
(ii) Premises																	
(iii) Scope of Business				1	1												2
(iv) Complaint of CHM/ Processed Herbal Medicines and Recall System																	
(v) Keeping of Records																	
(C) Wholesalers in pCm																	
(i) Personnel		2		21				2								11	36
(ii) Premises																	
(iii) Scope of Business				1										1			2
(iv) Complaint of pCm and Recall System																	
(v) Keeping of Transaction Documents																	
(D) Manufacturer in pCm																	
(i) Personnel	2	2		7		1	4			1						4	21
(ii) Factory																	
(iii) Fittings & Equipment																	
(iv) Scope of Business				4			1						1				6
(v) Complaint of pCm/Intermediate Products and Recall System																	
(vi) Keeping of Records																	
(E) CMT convicted of offence(s) punishable with imprisonment																	
	5	32	1	32	4	3	6				1						84
Total	7	38	1	77	8	6	13	4	1	1	1	1	4	3	25	190	

Explanatory Notes

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 the processing of herbal medicines according to business needs, preparing or compounding preparations for individual patients according to prescriptions given by CMPs and dispensing single Chinese medicine granules for prescription
- Keeping of Records : The retailers of CHM should keep the transaction documents and dispensing records of Schedule 1 medicines of the Chinese Medicine Ordinance

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 processing of herbal medicines according to business needs, and sale of single Chinese medicine granules for prescription
- Complaint of CHM/ Processed Herbal Medicines and Recall System : The wholesalers of CHM should set up and maintain a system of complaint and recall to enable the rapid and, as 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 wholesalers of CHM should keep the transaction documents as well as purchase and sales records of Schedule 1 herbal medicines of the Chinese Medicine Ordinance

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 wholesalers of pCm should provide suitable premises for the wholesale business in pCm including the business area and warehouse

Explanatory Notes

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 wholesalers of pCm should set up and maintain a system of complaint and recall to enable the rapid and, as 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, and should communicate such information to the Medicines Board as soon as possible
Keeping of Transaction Documents	:	The wholesalers 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
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 manufacturers of pCm should provide suitable premises for the manufacture, examination and storage of pCm/intermediate products
Fittings & Equipment	:	The manufacturers 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 manufacturers 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, as 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, and should communicate such information to the Medicines Board as soon as possible
Keeping of Records	:	The manufacturers of pCm should make proper records and keep relevant documents of purchasing ingredients, operation of manufacturing process, and transaction of pCm/intermediate products