

LCQ18: Regulating the sale of pharmaceutical products

Following is a question by the Hon Chan Hoi-yan and a written reply by the Secretary for Food and Health, Professor Sophia Chan, in the Legislative Council today (November 6):

Question:

Under the Pharmacy and Poisons Ordinance (Cap. 138), only "authorized sellers of poisons" may carry on a business of retail sale of pharmaceutical products containing poisons (including those in Parts 1 and 2 of the Poisons List), and only registered premises of such type of sellers (pharmacies) may use Chinese names comprising the term "藥店". Apart from such type of sellers, operators of shops holding a "listed seller of poisons" licence (medicine stores) may also sell pharmaceutical products containing poisons in Part 2 of the Poisons List. Some pharmacists have relayed that retail shops with Chinese names comprising terms such as "藥舖", "藥房" and "藥店" (other drugstores) have mushroomed in recent years. While a majority of those stores are not operated by the aforementioned two types of sellers, their names easily lead members of the public and tourists into mistaking them for being authorised to sell controlled pharmaceutical products, resulting in a lack of protection for consumers' rights and interests. In this connection, will the Government inform this Council:

(1) of (i) the respective year-end numbers of pharmacies and medicine stores and (ii) the respective numbers of pharmacies and medicine stores which were opened and closed down, in each of the past 10 years (with a breakdown by District Council district);

(2) of the respective numbers of complaints against pharmacies and medicine stores received by the Department of Health in each of the past five years;

(3) whether it has compiled statistics on the current number of other drugstores; if so, of the details; if not, the reasons for that and the difficulty involved;

(4) of the number of prosecutions instituted in each of the past five years by the authorities against operators of retail shops selling medicines, with a breakdown by type (i.e. pharmacies, medicine stores and other drugstores) and the offence involved; and

(5) whether it will consider amending the legislation to step up the regulation of other drugstores, including prohibiting them from using Chinese names comprising the character "藥", so as to avoid causing confusion to members of the public and tourists; if so, of the details; if not, the reasons for that?

Reply:

President,

Under the Pharmacy and Poisons Ordinance (Cap. 138) (the Ordinance) and its subsidiary legislation, the Pharmacy and Poisons Regulation (Cap. 138A), pharmaceutical products must meet the requirements of safety, efficacy and quality, and must be registered with the Pharmacy and Poisons Board of Hong Kong (the Board) before they can be sold or distributed in Hong Kong. The Department of Health (DH), in accordance with relevant legislation, adopts a risk-based approach in laying down a set of comprehensive and stringent control measures to regulate the manufacture, import, wholesale and retail of pharmaceutical products.

Having consulted the DH, reply to the question raised by the Hon Chan Hoi-yan is as follows:

(1) The number of licences (as at the end of each year), new licences and applications for withdrawing licences of Authorized Sellers of Poisons (ASP), commonly known as "pharmacies", and Listed Sellers of Poisons (LSP), commonly known as "medicine companies", in the past ten years are as follows:

Year	Number of licences		Number of new licences		Number of applications for withdrawing licences	
	ASP	LSP	ASP	LSP	ASP	LSP
2010	546	3 499	67	272	38	170
2011	557	3 572	47	283	36	211
2012	570	3 827	45	377	32	162
2013	597	3 907	106	701	79	621
2014	605	3 951	39	311	31	267
2015	607	4 012	34	277	32	216
2016	604	3 937	29	231	32	306
2017	614	3 937	37	258	27	258
2018	641	3 937	50	264	23	264
2019 (January to September)	665	4 299	48	545	24	183

The DH does not have the breakdown of number of licences of ASP and LSP by District Council districts. As at end-September 2019, the number of ASP and LSP on Hong Kong Island, in Kowloon and in the New Territories are as follows:

	Hong Kong Island	Kowloon	New Territories	Total
ASP	128	261	276	665
LSP	828	1 513	1 958	4 299

(2) and (4) The DH conducts surprise inspections of premises of ASP and LSP, as well as test purchases of controlled medicines, with a view to monitoring their compliance with the law and respective code of practice.

Should there be any contravention of the relevant legislation by drug retailers, the DH will take follow-up actions immediately and, on the advice of the Department of Justice, institute prosecution when there is sufficient evidence. Convictions by licensed retailers would be submitted to the Board for consideration of disciplinary action. Convictions by ASP usually involve illegal sale of Part 1 poisons and prescription medicines; whereas convictions by LSP or other premises usually involve illegal possession and sale of unregistered pharmaceutical products and Part 1 poisons.

The number of enforcement actions by the DH against ASP and LSP, and relevant complaints received by the DH in the past five years are as follows:

Year	Number of inspections		Number of test purchases		Number of convicted cases			Number of complaints	
	ASP	LSP	ASP	LSP	ASP	LSP	Other premises	ASP	LSP
2015	1 214	7 977	4 136	3 008	24	3	5	86	36
2016	1 209	7 956	3 955	4 021	15	4	4	82	27
2017	1 220	7 874	4 329	3 229	13	5	4	103	34
2018	1 212	7 814	4 194	3 350	14	5	3	100	22
2019 (January to September)	759	5 538	3 036	2 460	10	6	7	58	17

(3) Under the Ordinance, only persons authorised by the Board as ASP are allowed to conduct relevant retail business of selling poisons (including poisons listed in Part 1 and Part 2 of the Poisons List at the Schedule 10 to the Regulation). In addition, persons who wish to conduct relevant retail business of selling poisons listed in Part 2 of the Poisons List must obtain a licence of LSP issued by the Board.

The Ordinance stipulates that terms such as "è-¥æ^ì", "pharmacy", "dispensary" and "drug-store" used in connection with premises will be deemed to be calculated to suggest that such premises are premises registered under the Ordinance as premises of an ASP and are under the control of a registered pharmacist. The Ordinance restricts the use of the title "è-¥æ^ì" that can

only be used for premises registered by an ASP. Failure to do so may constitute an offence. Upon conviction of this offence, a person is liable to a maximum penalty of a fine of \$100,000 and imprisonment for two years.

Retailers of registered pharmaceutical products that contain uncontrolled ingredients do not require a licence. The DH does not have figures on these premises.

(5) Although retailers of registered pharmaceutical products that contain uncontrolled ingredients do not require a licence, the DH has implemented the following measures to regulate medicine retailers based on existing legislation and to enhance public education:

(a) the DH has an established mechanism in place to conduct test purchases at drug retailers, including ASP, LSP and other retail premises, to monitor their compliance on illegal sale of controlled drugs. Prosecutions would be initiated if contraventions of the laws are found;

(b) if the DH receives information suggesting that someone is suspected to have violated the Ordinance and its subsidiary legislation (including the suspected illegal sale of medicines, the use of restricted title "pharmacy" or the display of the prescribed pharmacy logo), investigation will be carried out immediately. Joint operation with the Hong Kong Police Force and the Hong Kong Customs and Excise Department will be conducted when necessary;

(c) to cope with the increasing number of retail premises engaged in the retail sale of drugs, the DH has stepped up its efforts in publicity and education to enhance public understanding of different types of drug retailers. Over 10 000 copies of education pamphlets on drug retailers and registered pharmaceutical products have been published for distribution to inbound tourists through the Hong Kong Tourism Board and the Travel Industry Council of Hong Kong, and to arriving passengers through sea, land and air control points; and

(d) the website of the Drug Office of the DH has listed out the name and address of all licensees (including ASP and LSP) for public information. The website also provides a search engine for members of the public to enquire if a premises holds a relevant licence.