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**Subcommittee on Chinese Medicine (Fees) Regulation,
Chinese Medicines Regulation and
Chinese Medicines Traders (Regulatory) Regulation**

Summary of views/Questions expressed by deputations

Section	Chinese Medicines Regulation
2	It is not clear whether the term "responsible person" mentioned in section 2 refers to an individual or a company
7	It is not clear whether the term "container" referred to in section 7 covers "百子櫃" which is commonly used by retailers of Chinese medicine
9(1) and (1)(b)	It is unfair that only registered Chinese medicine practitioners are allowed to prescribe Chinese herbal medicines specified in Schedule 1 of the Chinese Medicine Ordinance, as stipulated in section 9(1) and (1)(b)
11(g)(i)-(iii)	Section 11(g)(i)-(iii) stipulating the duties of holders of wholesaler licences in processing Chinese herbal medicines in their premises are not stringent enough to ensure public safety
15(c)	The term "active ingredient" referred to in section 15(c) should be replaced by "chief ingredient" to give clearer guidance to the trade, given that numerous and different kinds of Chinese herbal medicines or any other materials of herbal, animal or mineral origin customarily used by the Chinese in manufacturing proprietary Chinese medicines are used in the manufacturing of proprietary Chinese medicines

15(h) or (i)	Either section 15(h) or (i) should be deleted, so as to reduce the operating costs of the trade
15(j)	Section 15(j) should be deleted, as there is no need for Hong Kong to have the package insert of a proprietary Chinese medicine for sale outside Hong Kong
24(a)	Section 24(a) should be amended to also include medicines which a wholesale dealer in Schedule 2 medicines have processed in his/her premises
30(2) and (3)	The term "or for such shorter period as considered appropriate by the Medicines Board" referred to in section 30(2) and (3) should be deleted
37(1)(c)	Section 37(1)(c) requiring the manufacturer of a proprietary Chinese medicine, which is administered for a particular patient, to notify the Medicines Board at least one working day before the day on which the manufacturing process begins should be deleted
Schedule 1	Section 1(b)(iii), (d)(ii) and (e)(iii) and section 2(a)(ii), (b)(iii), (d)(ii) and (e)(iii) of Schedule 1 stipulating the minimum qualification of responsible persons in the opinion of the Medicines Board should be more clearly spelt out
Schedule 3	Schedule 3 prescribing the form of a certificate of sale of proprietary Chinese medicine should be amended by removing the manufacturer(s) name and item (b) which certifies the premises in Hong Kong in which the proprietary Chinese medicine is manufactured are subject to inspections. This is because firstly, most of the proprietary Chinese medicines exported overseas are manufactured in the Mainland. Secondly, there is no need to disclose to the overseas buyers who the manufacturers are, as such information is commercial secret

Item	Chinese Medicine (Fees) Regulation
11	The fee of $26,650 for issue of a certificate for manufacturer (Good practices in manufacture) is too high
17	Fee for application for variation of registered particulars of a registered proprietary Chinese medicine at $1,790 is too high, having regard to the fact that the fee for registration of a proprietary Chinese medicine is at most $2,000

Chinese Medicine Traders (Regulatory) Regulation
Procedures to be adopted by the Regulatory Committee of Chinese Medicines Traders and the Chinese Medicines Board in dealing with complaints are too complicated and time-consuming

Other comments/questions
- Enforcement of the Chinese Medicines Regulation and Chinese Medicine Traders (Regulatory) Regulation should not be too stringent in the beginning, so as to allow more time for the trade to comply with the requirements; - The Administration should set up a telephone hotline to answer enquiries from the trade; - The four sets of practising guidelines should be promulgated as soon as possible, and there should be a formal mechanism to allow the trade to give its view on the practising guidelines; - The Administration should step up its efforts to minimise or eradicate counterfeit and contraband Chinese medicines; - Transitional period should be extended to allow more time for the trade to comply with the requirements; - Whether there is a list of approved local and overseas laboratories; if so, when could the list be promulgated to the trade; - Does the Administration have adequate skilled staff - (a) to handle the voluminous applications for registration of proprietary Chinese medicines; and (b) to carry out the enforcement work; - Whether there is a mechanism to handle consumer complaints and address the issue of responsibility after the registration of proprietary Chinese medicines; - Would tests conducted by approved Mainland laboratories be recognised in Hong Kong, thereby obviating the need for proprietary Chinese medicines, which have passed testing in the Mainland, to undergo testing by a local laboratory before they could be registered in Hong Kong;

- Whether the Administration would help the manufacturers of proprietary Chinese medicines to meet the requirements stipulated in the Chinese Medicines Regulation, as well as to render assistance to people who are made redundant because of the failure of their employers to get their products registered under the Chinese Medicines Regulation;

- Inspection of manufacturers of both Chinese and western medicines should be conducted simultaneously. Similarly arrangement should be applied to a company which holds both a retailer and a wholesaler of Chinese medicine licences;

- Application process for a person who needs to apply for both retailer and wholesaler licences of Chinese medicines should be made more convenient;

- Whether the Administration would consider allocating funds to help the trade to improve its facilities; and

- Whether the Administration would consider running free training courses for people working in the Chinese medicine industry.

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