Economic and Employment Council
Retail Task Force

Regulatory review of the beauty products/cosmetics/medicine retail categories

Purpose

This paper presents the views of the trade on regulatory activities affecting the beauty products/cosmetics/medicine categories of the retail trade.

Introduction

2. Beauty products/cosmetics/medicine stands next in the 2005 review programme of the Retail Task Force. The review does not cover Chinese medicine as its regulations were introduced only a year ago. Preliminary meetings had been held with relevant retail operators and trade associations to discuss their concerns and perceived issues. Backgrounds of regulatory activities and related views of trade are summarised below to set the scene for discussion by Members.

Cosmetics

3. At present, cosmetics are free to enter the Hong Kong market so long as they comply with the controlling standards of their exporting countries. Through this laissez-faire policy, Hong Kong has developed into a retail hub for world-wide cosmetics. Locally distributed cosmetics are mainly imported from Europe, USA and Japan, which already have tough requirements on product safety and other attributes. Therefore, they are safe to use when product cautionary advice is observed.

Intervention by the Administration

4. A major concern of trade is the regulatory proposal on volatile organic compounds (VOCs). The proposal in its initial form had failed to reckon that Hong Kong was too small a market to influence any sizable manufacturer. The recent development on the subject is welcomed by the trade, especially in relaxing the proposed control over consumer items containing VOCs.

Beauty products/health food

5. There is no regulatory requirement on beauty products/health food not containing prohibited or medicinal/drug ingredients. The sale of health food containing prohibited ingredients is forbidden. Products with medicinal/drug ingredients are required to register as pharmaceutical products or substances. Discreet traders often consult relevant authorities on the need for registration before product launching.

Regulatory control for health food

6. The role and authority of the Department of Health (DH) and the Food and Environmental Hygiene Department (FEHD) in controlling health food are not clearly defined and cause confusion to the trade. There were occasions that DH/FEHD referred enquiries to the other department when it was approached on the need for registration of a health product.

7. There is no clear guideline on the kinds of health products that need registration. For example, food supplements made of uncommon herbs do not require registration, whereas common products with Omega 3 or evening primrose would have to register.

8. Trade has to provide substantial supporting documents so that DH could determine if a product needs registration. The confirmation process takes an average of 3 to 6 months and no interim reply is given to update the enquirer of the status. The registration process takes another 6 months and tests in support of registration can be expensive. On the whole, the processes prevent timely launching of products.

9. Initial feedback from DH is that the confirmation process only requires composite formula, sample, sales pack and insert/leaflet of a product. There is no pledge for the process. Normally, confirmation is given in 6 to 8 weeks. If registration is needed, the process for registering pharmaceutical products will apply and DH has pledged to complete the process in 5 months.

Restrictions on product ingredients

10. Common beauty products such as hand-creams, face wash, hand soaps, and liquid soaps are subject to a 6-month registration process when they feature an anti-septic element. Besides, a health food commonly sold in overseas countries could not be sold in Hong Kong if the preservative it contains is not in our approved list.

Medicine

11. Under Cap 138 Pharmacy and Poisons Ordinance (the Ordinance), medicine retail outlets are required to apply for a Certificate of Registration of Premises of an Authorized Seller of Poisons or a Licence for Listed Seller of Poisons in order to operate.

12. In the case of registration of premises of an authorized seller, DH will contact the applicant within two weeks of application to fix a date for interview, and conduct a site inspection of the business premises within one week if the applicant passes the interview. If everything is in order, the Pharmacy and Poisons Board (PPB) Secretariat will sign the certificate in 10 to 14 days. For listed sellers, the Pharmacy and Poisons (Listed Sellers of Poisons) Committee established under the PPB will consider the application without the need to interview the applicant. The Committee generally meets once a month. DH has pledged that both applications for Registration of Premises and Licence for Listed Seller are approved within two months of application.

13. New pharmaceutical products have to be registered with PPB before they can be put to sale. The Registration Committee of PPB examines and approves applications for registration and the Poisons Committee determines the categorization of approved pharmaceutical products. The PPB will endorse the recommendations of both committees. The Registration Committee, the Poisons Committee and the PPB meet in consecutive months throughout the year for product registration. DH has pledged to complete the registration process for drugs within 5 month, and 95% of the applications meet the performance pledge. Drugs that cannot meet the pledged time are mainly products with new chemical entities which require an additional 3 to 6 months to amend the legislation. Some operators opine that the current registration process is too long.

14. In general, the trade considers that the regulations on dispensing have caused inconvenience to patients and are outdated when compared to overseas practices. Various concerns raised by trade are summarised below.

<u>Restrictions on dispensing prescriptions</u>

15. Under the regulations of the Ordinance, partial dispensing is not allowed unless specifically stated in the prescription. This would refrain patients from partial filling of expensive prescription at different times; restrict subsequent dispensing of refill prescription to the pharmacy that

dispensed the prescription for the first time; and confine dispensing of multiple items in a prescription to a single pharmacy.

16. When a drug has been prescribed in brand name, generic drug of a different brand cannot be used for dispensing. Such restrictions would deprive patients of choices.

17. The regulations also specify that pharmacists cannot clarify details of a prescription with doctor over the phone. A patient will have to go back to the doctor to amend an incomplete/illegible prescription before the pharmacist can do the dispensing. Besides, Part I poisons can only be sold on the condition that buyers record their personal particulars such as name, identity card number on the poisons book kept by individual pharmacy for inspection by the authority.

Requirements for pharmacy setup

18. Trade has cited the following to demonstrate the impractical and outdated requirements of the existing regulations –

- Provision of running water and drainage at pharmacy counter;
- Display of prescribed form of pharmacy logo of fixed dimensions; and
- Inclusion of home address in pharmacist's certification.

Classification of drugs

19. The classification of drugs in the pharmacy and poisons schedule is only in chemical names. In reality, both the public and pharmacists are more familiar with pharmaceutical names.

20. Medicines are classified into "poisons" and "non-poisons". Such description causes confusion and uneasiness to patients. In other countries, the description for "poisons" has been replaced with "prescription" for a long time. Furthermore, the legal classification of drugs in the schedules under the Ordinance *(e.g. Part I Schedule 1, Part II, Dangerous Drugs)* is difficult to be identified and understood by pharmacists and consumers. In UK, all medications are classified and marked in terms of conditions under which they can be sold (e.g. general sales, pharmacy only, prescription only and controlled drugs).

Disposal of expired/damaged drugs

21. Part I poisons of the Ordinance requires expired/damaged drugs to be disposed of through service providers approved by the Environmental Protection Department. For dangerous drugs, they have to be disposed directly to the Nam Cheong Office of DH. The trade considers that the current requirements rigid when compared to overseas countries.

Licensing requirements

22. Business Registration Certificate is a pre-requisite for registration as authorized seller (commonly known as "Pharmacy Licence") or licensing as listed seller of poisons. In a normal business setup, business registration is needed within one month upon commencement of business. But in order to obtain the registration/licence for selling medicine, pharmacies have to apply for business registration well advance of other trades.

23. In applying for the "Pharmacy Licence", both the pharmacist and the person-in-charge of the store *(i.e. store manager)* are required to attend an interview with DH staff. Trade is not clear about the purpose of interviewing the store manager. The interview is normally conducted in the second week after the submission of an application. Trade has suggested that the interview be conducted sooner.

Undesirable Medical Advertisements Ordinance (UMAO)

24. Trade has proposed that DH advises traders about the application of UMAO. Relevant guidelines should be provided to help operators and the advertising industry avoid breaking the law unintentionally.

Common issues and concerns for cosmetics, beauty products/health food

25. In addition to the above, retail operators of cosmetics, beauty products/health food sectors have also proposed improvement in the communication between trade and relevant authorities. This is particular useful when the authority introduces new control measures. Trade would wish to be informed even if the new measures are directed at manufacturers.

Way forward

26. Members are requested to comment on the issues and concerns raised by trade and give views on the way forward for the regulatory review on the retail category of beauty products/cosmetics/medicine.

EEC Subgroup on Business Facilitation Secretariat
October 2005