

**Business Facilitation Advisory Committee
Retail Task Force**

***Update on Improvement Measures in Response to Concerns of Trade in
the Beauty Products/ Cosmetics/ Medicines Retail Categories -
September 2007***

Purpose

This paper provides an update on improvement measures in response to trades' concerns in the beauty products/cosmetics/medicines retail categories.

Overview

2. Following the last Retail Task Force (RTF) meeting held on 14 May 2007, the Secretariat has invited the trades to provide their feedback on the updated response of the Department of Health (DH) on the progress of improvement proposals as outlined in RTF Paper 34. Seven of the 13 trade associations had no further comments, whilst the remaining six¹ basically reiterated their previous concerns. In general, the trades appreciate RTF's good efforts and DH's positive response to address their concerns. The improvement measures undertaken by DH are on the whole well received, but the trades have called on the Administration for a holistic review and revamping of the existing regulatory framework governing drug registration and medical advertising to better meet the needs of the trade and the community at large. They consider it important for the Administration to continue improving communication with the trades, e.g. through establishing business liaison group.

¹ The six associations include one cosmetics and perfumery association, one direct selling association, one suppliers association, one association of pharmaceutical industries, one health food association and one pharmaceutical distributors association.

3. The Secretariat has passed the trades' further comments and the Task Force's views to DH for consideration. DH has updated the progress and provided its response as summed up below. The subject Chief Pharmacist of DH will attend the forthcoming Task Force meeting to brief the Task Force.

4. In recent exchanges with the trade, the health food industry reiterated that vitamins, minerals and health supplements should be treated differently or excluded from registration. The cosmetics industry and pharmacies also suggested relaxing cosmetics and common products like antiseptics from registration. As suggested by the RTF, the Secretariat is working with the trades to come up with a proposed list of beauty/health products which might be exempted from the registration requirements for DH's consideration. Replies from a number of trade representatives are pending. DH has agreed to consider the proposed list, and incorporate any changes in the guidelines being finalized.

Progress

5. In general, DH is open to improvement measures proposed by the RTF and the trades, and is committed to continuing with its efforts to facilitate business while safeguarding public interests in performing its regulatory role. Some notable developments/achievements include –

- (i) With the implementation of a number of improvement measures as recommended by the RTF, the registration time for pharmaceutical products containing New Chemical Entities (NCE) has been reduced from seven months in mid-2005 to 5.5 months by June 2007, representing a 20% reduction;
- (ii) DH has given priority to processing applications for re-registration involving only change of formula and change of name. A set of new guidelines on re-registration requirements was issued in September 2007;

- (iii) DH has recently refined the guidance notes on registration of pharmaceutical products, and issued the revised notes in September. Applicants are encouraged to make enquiries with the subject officer of DH about progress of their applications at any time during the application process, if necessary;
- (iv) DH has consulted the trades in discussing the criteria for classifying medical/beauty/health products as pharmaceutical products. It will consider the proposed list being coordinated by the Secretariat before finalizing the guidelines on beauty/health products that need registration;
- (v) DH is considering the feasibility of adopting a differential approach in registering products of different risk categories (*such as vitamins, minerals, health supplements, antiseptics, etc.*) in the context of finalizing the guidelines. It will consider further suggestions from the trades with reference to the proposed list to be provided by the Secretariat;
- (vi) The Pharmacy and Poisons Board (P&P Board) has agreed to seek the Legislative Council's approval to amend the law to remove nicotine replacement therapies from Part I to Part II of the Poisons List, making them available for self-selection by members of the public instead of from dispensaries only and through a pharmacist, provided that the manufacturers of these products have improved the labelling of the products to facilitate self-selection. The manufacturers are making such improvements; and
- (vii) To facilitate the trade in understanding the classification of drugs, DH is finalizing a guide on the chemicals covered by the Poisons List. The guide will be released to the pharmacy practitioners at the end of September 2007, and be uploaded on DH's website for easy access.

DH's response to the comments of the trades and the RTF

6. DH's response to the specific comments of the trades and the RTF is summed up at **Annex**.

Way forward

7. Members are invited to note the progress made in implementing the improvement measures and give views on the latest response/improvement measures undertaken by DH.

Business Facilitation Advisory Committee Secretariat
September 2007

DH's response to the comments of the trades and the RTF

I) Lack of guidelines on beauty/health products that need registration

Trade's views

- Two associations requested DH to further consult the trade before finalizing the guidelines.

RTF's views

- DH should consider establishing a performance pledge for determining whether a health product needs registration, and evaluate the effectiveness of the guidelines two to three months after their issue.

DH's response

- DH is open to the idea of consulting the trade again on a need basis before finalizing the guidelines for issue. DH will review the effectiveness of the guidelines six months after the introduction.

II) Long processing time of registration

Trade's views

- One association reiterated that the Administration should revamp the current outdated regulatory framework governing the registration of pharmaceutical products. It questioned the need to seek approval from the Legislative Council in the registration process. It suggested that DH should further increase the number of P&P Board meetings by calling monthly P&P Board meeting on a need basis whenever there is a new pharmaceutical product to be approved or matter to be discussed.

DH's response

- As earlier explained to the RTF and the Business Facilitation Advisory Committee (BFAC), the Administration currently does not have immediate plans to revamp the Pharmacy and Poisons Ordinance due to competing priorities. The Administration considers it appropriate to maintain the existing legislative process, which introduces transparency and public scrutiny into the registration system. However, the

Administration would continue to make necessary arrangements to ensure timely introduction of legislative amendments and to avoid the recess of the Legislative Council.

- The suggestion for the P&P Board to hold monthly meetings on a need basis will be referred to the Board for consideration.
- The drug registration process has been reviewed several times in recent years, resulting in streamlined procedures and shorter processing time. Subject to availability of resources, DH will look out for opportunities to conduct another comprehensive review.

Trade's views

- An association complimented DH for having expedited the registration process of pharmaceutical products containing NCE. It supported increased manpower for product registration, noting that DH had recently taken longer time to process applications for change of particulars (*i.e. from three to four months to five to six months*) and applications for clinical trial certificate (*i.e. from 12 weeks to 16 weeks*).

DH's response

- Overall workload is on a rising trend. The number of applications for clinical trial certificates has increased. A bid for manpower increase to strengthen drug registration service has been made and the outcome is awaited.

Trade's view

- On registration delay arising from non-compliance of labelling requirements, one association considered that DH should provide more specific advice to help the trade resolve individual cases.

DH's response

- The trade may approach DH for specific advice if they need any clarification on individual cases. DH stands ready to listen to the suggestions of the trade as to how the labelling guidelines can be improved. DH is awaiting the trade's further suggestions.

Trade's view

- One association attributed the long processing time for product registration to heavy demands on the Government Laboratory's service and long waiting time for the Government Laboratory to analyse samples. It supported the allocation of more resources and manpower to strengthen the Government Laboratory's service.

DH's response

- Applicants can either provide the required analytical report by engaging private laboratories or provide product samples for analysis by the Government Laboratory. In September 2006, the Registration Committee (RC) under the P&P Board re-issued to the trade the criteria of accreditation of laboratories that can take up the role of drug sample analysis in lieu of analysis by the Government Laboratory. The RC has decided to exempt drugs that have been tested by competent overseas authorities from local laboratory test.

III) Restriction on product ingredients

Trade's views

- One association stressed that it would be in the interests of the trade and the public to impose a less stringent registration process on vitamins, minerals and supplements or to exclude them from registration. It also proposed to relax external personal care products, such as anti-dandruff, anti-acne, anti-bacteria, anti-plague, anti-gingivitis, etc. from registration.

DH's response

- The proposal will be considered in the context of finalizing the guidelines.

IV) Classification of drugs

Trade's views

- One association reiterated that the term "poison" as a description for medicines and the classification descriptions such as "Part I" and "Part II" drugs were misleading and difficult to understand. It urged the authorities to adopt a more user-friendly classification description as soon as possible.

DH's response

- The trades have been consulted. Legislative amendments are being considered to replace the term “poison” on the labels of some pharmaceutical products with more user-friendly terms.

V) Advertising health/medical products

Trade's views

- One association reiterated that the current restriction on the advertising of pharmaceutical products was outdated and unfair, depriving consumers and patients of their right to know. It urged the Administration to revamp the Undesirable Medical Advertisements Ordinance (UMAO) and the Codes of Practice of the Broadcasting Authority restricting advertising of pharmaceutical products on television and radio. It considered that the classification of smoking cures as restricted medical products/services under the Codes was contradictory to the Government's anti-smoking policy.

DH's response

- The UMAO, which prohibits the advertising of medicines for the prevention or treatment of a list of named diseases, is necessary for protecting the public against any harm that might arise from improper self-medication, thereby allowing the disease to worsen and delaying proper treatment. As explained earlier to the BFAC and the RTF, the Administration considers it important to regulate relevant health claims to protect members of the public and does not have immediate plans to review the provisions in the UMAO at this stage.

RTF Secretariat's observations

- As regards the Codes, the Secretariat of the Broadcasting Authority Codes of Practice Committee (serviced by the Television and Entertainment Licensing Authority) is considering whether revision to the relevant paragraph of the Code is necessary in response to a licensee's request for review of the Code governing advertising of smoking cure on television.

VI) More communication with the trade

Trade's views

- Two associations called on DH to set up a business liaison group to maintain regular communication with the trade.

DH's response

- Regular meetings are being held with the known trade associations at least once a year, while special meetings are held as and when necessary.

VII) Representation of the PPB and its committees

RTF's views

- Consideration should be given to broaden the representation of the PPB and its committees to include members from the trade associations of health food/beauty products.

DH's response

- This suggestion will be referred to the P&P Board for consideration.

VIII) Long processing time of re-registration

RTF's views

- DH should set up a performance pledge for re-registration and expedite the processing time for re-registration.

DH's response

- This is being considered with reference to the actual time taken for re-registration after the release of the guidelines in September 2007.

IX) Restrictions on dispensing prescriptions

RTF's views

- To legitimize clarification of prescription details over the phone between registered pharmacists and doctors, DH should consider accepting records of prescription kept by doctors in lieu of copy of prescriptions.

DH's response

- As the law does not require doctors to keep such records, this suggestion may not be workable.