

**Eleventh Meeting of
the Business Facilitation Advisory Committee**

Agenda Item 3(a) : Report on the work of the Retail Task Force

Purpose

This paper reports on the work of the Retail Task Force (RTF) since the last Business Facilitation Advisory Committee (BFAC) meeting on 31 March 2009.

Work progress of the RTF

Regulatory review of the beauty products/cosmetics/medicine categories

2. The Department of Health (DH) has further streamlined the procedures to expedite the processing of applications for registration of pharmaceutical products. It has made steady progress in clearing backlog and reduced the registration lead-time. The improvement measures are generally well-received by the trade.

3. DH reported the major developments as follows –

- (a) A review on the effectiveness of guidance notes on classification of products as “pharmaceutical products” showed that the trade was generally satisfied with the clarity of the guidance notes;
- (b) To improve the efficiency of pre-registration product classification, DH had been holding monthly consultation sessions with the distributors of health products to clarify their queries directly since March 2009. So far, five monthly consultation sessions were held with the trade. The trade’s feedback was positive. The new arrangement was considered effective;
- (c) The registration lead-time was shortened from four months to two months following the waiver of the requirement for analysis of a sample of pharmaceutical product by an accredited laboratory or

the Government Laboratory prior to registration approval with effect from 1 January 2009, and the provision of three additional pharmacists for registration approval duties since March 2009;

- (d) DH would consider deploying necessary manpower to expedite the processing of applications for change of registered particulars of a registered pharmaceutical product¹, and consider setting a relevant performance pledge in due course; and
- (e) The registration requirements of beauty/health food products had been relaxed. Nearly all personal care products such as anti-septic products, anti-bacteria products and body washes were exempted from registration as pharmaceutical products subject to the fulfillment of specific conditions. Special exemptions were provided for the routine quality analysis of products containing vitamins, minerals, etc. The trade's general feedback on the relaxation was extremely positive.

4. DH assured the RTF that it would continue monitoring the effectiveness of the relaxation measures, and working with the RTF and the trade for continuous improvement of our pharmaceutical product regulatory regime.

Concerns of the proprietary Chinese medicine (pCm) trade

5. DH reported that steady progress was made in pCm registration. The Chinese Medicines Board (CMB) under the Chinese Medicine Council of Hong Kong (CMC) had assessed all the applications for transitional registration. Around 9 000 applications were issued with the "Notice of confirmation of transitional registration of pCm". The CMB was considering about 640 applications for review and awaiting replies for supplementary information from about 1 100 assessed cases. An implementation plan for commencement of section 119 of the Chinese Medicine Ordinance (CMO) was being worked out and the trade would be consulted later.

¹ Re-registration of pharmaceutical products will be required only if there is a change of product name, product composition or dose form (e.g. from tablet to capsule). The current performance pledge for both registration and re-registration of pharmaceutical products is five months. If the trade intends to change any other particulars of the product included in the registration (e.g. the name and address of the manufacturer or the registration certificate holder), prior approval will have to be sought from DH. There is currently no performance pledge on processing change of registered particulars.

6. To facilitate the trade in fulfilling the requirements of label and package insert for pCm registration, the CMB has recently uploaded the guidelines on the label and package insert requirements onto the CMC website for the traders' reference.

7. To better understand the trade's concerns about difficulties encountered in conducting quality tests and explore ways to address their problems, DH and the Chinese Medicines Committee under the CMB held another meeting with the Chinese medicines traders associations and the laboratories concerned on 9 March 2009. In the meeting, the trade was provided with supplementary information on how to establish quality specification with reference to the advice obtained from experts. The CMB has been informed of the traders' concerns. If the traders fail to submit the required testing reports for their products by 30 June 2009, the CMB will take into account their difficulties on a case-by-case basis when considering their applications. Further meetings to facilitate communication with the trade will be arranged.

8. The Administration assured the RTF that it would take into account all relevant factors, including the possible impacts on the trade and the public, the readiness of the trade and the availability of laboratories services to support compliance by the trade, before the commencement of section 119 of the CMO.

Nutrition Labelling Scheme

9. Since the passage of the Amendment Regulation by the Legislative Council in mid-2008, the Administration has implemented a series of measures (including guidance notes and frequently asked questions, basic and advanced trade workshops, telephone enquiry service, nutrition label calculator and laboratory support) to facilitate legal compliance by the trade and to promote public understanding of the Nutrition Labelling Scheme.

10. Some trade representatives requested the Centre for Food Safety (CFS) of the Food and Environmental Hygiene Department (FEHD) to grant approval to all products eligible for small volume exemption (SVE) by the end of 2009 on the understanding that certain major retailers would not accept delivery of products that did not comply with the Nutrition Labelling Scheme. The CFS organized a meeting on 2 June 2009 to consult the trade of the operational details of the special arrangement of accepting SVE application starting from September 2009. The CFS's operation plan was

generally supported at the meeting. The CFS plans to proceed with the special arrangement as follows –

- (a) Application forms will be available in mid-August 2009 and the CFS will begin processing SVE application on 1 September 2009;
- (b) Applications will be processed on a first-come-first-served basis. The CFS will respond to the applications as soon as possible, and for applications submitted before 31 October 2009, the applicants will be informed of the results no later than 18 December 2009, provided that all necessary supporting information is submitted; and
- (c) Successful applicants will be required to pay the exemption fee within a specified period in July 2010 for the exemption to take effect on 1 July 2010.

11. The trade welcomed the advancement of the timeframe for accepting SVE applications. They requested the Administration to address their remaining concerns about implementation details. Some major concerns include –

- (a) whether the CFS would have sufficient capacity to complete processing around 15 000 to 20 000 SVE applications by the end of this year;
- (b) inadequate time to clear stock not labelled in accordance with the legal requirements before the effective date of 1 July 2010;
- (c) inadequate laboratory support;
- (d) potential enforcement and compliance issues arising from variation of testing results; and
- (e) handling of food items already put on the market if the exemption in relation to the subject products was revoked for exceeding the 30 000-unit exemption limit.

12. The RTF urged the CFS to further refine the related procedures and requirements to make the SVE arrangement more business-friendly and continue to work closely with the trade to address their needs and facilitate their compliance.

13. The CFS assured the RTF that it would continue to work with the trade to thrash out the implementation details and explore possible ways to accommodate the trade's concerns.

14. To have an overview on the impact of the Nutrition Labelling Scheme on the availability of prepackaged food in the market, the CFS will conduct surveys before and after the implementation of the relevant Amendment Regulation. The first survey will commence before October 2009.

Introduction of a composite licence for the manufacture/sale of various types of ready-to-eat food items

15. FEHD reported that the proposed composite licence system was intended to allow greater flexibility to the trade so that applicants could choose any combination of the specified food items to suit their operational requirements and manage the risks associated with different food types. The composite licence was a new food business licence and required a new fee charging mechanism. FEHD had recently obtained the agreement of the Financial Services and the Treasury Bureau to model the fee levels for composite licence on the existing fee scale for a food factory licence. The fee for a composite licence for each of the 19 area bands (based on the area of the premises) would be pitched at the average of the urban and NT fees of the food factory licences of corresponding area bands. Introduction of the composite licence would require legislative amendments to the Food Business Regulation and related subsidiary legislation. FEHD was seeking the advice of the Department of Justice and would soon finalise the drafting instructions, with a view to tabling the necessary legislative amendments in the first half of the 2009-10 legislative session.

Environmental levy scheme on plastic shopping bags

16. The Product Eco-responsibility (Plastic Shopping Bags) Regulation was approved by the Legislative Council on 23 April 2009 and gazetted on 24 April 2009. The registration of "prescribed retailers" has begun on 30 April 2009, with a view to fully implementing the environmental levy scheme on 7 July 2009.

17. The Environmental Protection Department (EPD) has offered registration seminars for the trade, as well as visits to and meetings with individual retailers, to facilitate the registration process. As at 5 June 2009,

EPD has received registration applications of 2 783 qualified retail outlets (or some 93% of potential qualified retail outlets). It is expected that all registration applications would have been received and processed by late June 2009, well ahead of the commencement date of 7 July 2009.

18. In parallel, EPD has also launched a comprehensive publicity campaign since May 2009 to raise public awareness on the environmental levy scheme and to encourage the adoption of “Bring Your Own Bag (BYOB)” green habit. In the run-up to the launch of the environmental levy scheme, the publicity would be further intensified. EPD will also set up a dedicated hotline (3187 0333) with extended operating hours from 7 July 2009 onwards to address public enquiries on the scheme.

19. EPD has undertaken to review the effectiveness of the environmental scheme after its implementation. EPD is conducting a survey at landfills and refuse transfer stations to take a snapshot on the disposal of plastic shopping bags, as well as other carriers, before the commencement of the levy scheme. Similar surveys will be conducted annually thereafter for comparison purpose. Aside from the surveys which ascertain the reduction at the disposal end, EPD will also closely monitor the quarterly returns submitted by registered retailers to ascertain the distribution at source. EPD will also conduct surveys to observe the change of public behavior and attitude after the implementation of the levy scheme. With these information, EPD will consider whether and how to extend the levy scheme to other retailers.

20. The RTF requested the Administration to review the effectiveness of the scheme in consultation with the trade, and consult the RTF before further extension of the scheme to other retailers.

Way forward

21. Members are invited to note the work progress of the RTF. The RTF will monitor the development of the issues.

Economic Analysis and Business Facilitation Unit,
Financial Secretary’s Office
July 2009