

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

Agenda Item 4(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 13 November 2008.

Work progress of the RTF

Regulatory review of the beauty products/cosmetics/medicine categories

2. In response to the RTF Convenor's appeal letter for more proactive and prompt action to address the trade's concerns, the Administration undertook to continue to work with the RTF and the trade for continuous improvement in the pharmaceutical product regulatory regime.
3. The Department of Health (DH) reported the following major developments –
 - (a) The registration time for pharmaceutical products containing New Chemical Entities (NCE) had been reduced from seven months in mid-2005 to 4.5 months by December 2008, representing a 35% reduction. The Hong Kong Association of the Pharmaceutical Industry, which represented the majority of pharmaceutical companies supplying mainstream pharmaceutical products in Hong Kong, was satisfied with the improvement;
 - (b) The Registration Committee (RC) of the Pharmacy and Poisons Board had waived the requirement for analysis of a sample of pharmaceutical product by either an accredited laboratory or the Government Laboratory prior to registration approval with effect from 1 January 2009. This was expected to shorten the registration lead time;

- (c) The DH had employed three additional pharmacists for registration approval duties. This would help clear existing backlog and further expedite the registration process; and
- (d) To improve the efficiency of pre-registration product classification, the DH would hold monthly consultation sessions with the distributors of health products to clarify their queries directly. This would replace the current practice of providing written direction to the trade's request for product classification.

4. The Food and Health Bureau (FHB) noted the RTF's suggestion that the Pharmacy and Poisons Ordinance (PPO) be revamped. The FHB advised that since enactment, the PPO and its subsidiary legislation had indeed been updated from time to time to keep pace with scientific and technological advancements and the changing needs of the community. For instance, the Pharmacy and Poisons Regulations were recently amended to relax the controls on the sale of most nicotine replacement therapies for smoking cessation. For the time being, the FHB did not have immediate plans for a major revamp of the PPO. The FHB assured the RTF that every effort would be made to update the Regulations as the need arose.

Concerns of the proprietary Chinese medicine (pCm) trade

5. In response to the RTF Convenor's appeal letter for more proactive and prompt action to address the trade's concerns, the Administration undertook to continue to work with the RTF and the trade in bringing improvements to the regulatory regime.

6. The DH reported that there had been steady progress in processing applications for pCm registration. As of January 2009, the processing of more than 11 000 applications for transitional registration had been completed, of which some 7 400 were issued with the "Notice of confirmation of transitional registration of pCm". The DH anticipated that the processing of applications for transitional registration would be completed in the coming months. As regards the applications for non-transitional registration, about 1 800 were issued with the "Notice of confirmation of (non-transitional) registration application of pCm". Around 1 000 applications had not yet submitted essential reports such as the product's quality specification and acute toxicity reports. The applicants concerned had been reminded to submit the necessary documents as soon as possible to facilitate further vetting of their applications.

7. The DH would work out an implementation plan for commencement of section 119¹ of the Chinese Medicine Ordinance after the completion of processing applications for transitional registration. All relevant factors, including the possible impact on the public, the readiness of the trade and the availability of laboratory services to support compliance by the trade, would be taken into account in considering the commencement date. The trade would be duly consulted before the plan was finalised.

8. To address the trade's concerns about technical difficulties involved in quality testing, the DH and the Chinese Medicines Committee under the Chinese Medicines Board (CMB) met with local laboratories in mid-October 2008. The local laboratories mainly expressed difficulties in finding suitable technical markers for quality testing and sought clarification on the appropriate method for quality testing. The DH would hold another meeting with the local laboratories in March 2009 and provide supplementary information on how to establish quality specification with reference to the advice obtained from experts in China.

9. To facilitate the trade in meeting the requirements for registration, the DH had been enhancing its communication with the applicants by conducting case conference when necessary, and would liaise with the trade associations to organise technical workshops on pCm testing for the traders and the testing laboratories.

10. Separately, the RTF noted that during the SME focus group meetings held on 5 December 2008, a trade representative had proposed that consideration be given to relax the licensing conditions of Chinese herbal medicines tradeshow licence. The DH clarified that if a holder of a retailer licence in Chinese herbal medicines (tradeshaw) wished to take part in a tradeshaw lasting for not more than 14 consecutive days, he only had to notify the CMB in writing at least one working day before the event. The RTF urged the Administration to consider whether this requirement could be waived in order to relieve both the trade and the DH of the administrative burden. The DH explained that the above arrangement had already served to strike a balance between safeguarding public health and facilitating the operation of the trade. Nonetheless, the DH undertook to convey the RTF's view for the consideration of the CMB.

¹ After the commencement of section 119 of the Chinese Medicine Ordinance, no person shall sell; or import; or possess any pCm unless the pCm is registered under section 121.

Nutrition Labelling Scheme

11. The RTF appreciated that the Centre for Food Safety (CFS) of the Food and Environmental Hygiene Department (FEHD) had initiated/implemented a series of measures (including guidance notes, enhanced frequently asked questions, basic and advanced workshops, telephone enquiry service, laboratory support and nutrition label calculator) to facilitate the trade to understand and comply with the new labelling requirements. However, the trade worried whether there would be sufficient time to comply with the labelling requirements. They claimed that in line with the existing trade practice, traders had to comply with the requirements at least six months before the commencement of the scheme, i.e. before 1 January 2010. They requested the CFS to expedite the handling of outstanding matters about the labelling requirements and pleaded for an extension of the implementation date of the scheme. As against the CFS' initial plan to accept applications for registration under the small volume exemption scheme three months before the commencement date of 1 July 2010, they also requested the CFS to advance the registration time with clear application guidelines as soon as possible, bearing in mind the large number of applications and complexity of the registration work. The RTF urged the CFS to fully consider the trade's comments and continue with its trade facilitation efforts.

12. The CFS assured the RTF that it would continue with its trade facilitation measures and strive to advance the registration time for the small volume exemption scheme as far as possible. The trade would be informed once the application details were finalized.

13. Concerning the feedback of laboratories personnel attending the workshops organized by the CFS, the CFS reported that local laboratories did not envisage any problem in conducting the nutrient tests. The participants of the workshops held in China were keen to learn more about the technical details of the nutrition labelling scheme and so far no testing problems, including the testing of trans fat, were raised.

14. The CFS confirmed that market surveys would be conducted to help assess the impact of the nutrition labelling scheme on pre-packaged food products.

Proposed Food Safety Bill

15. The FHB briefed the RTF on the results of the public consultation on the proposed Food Safety Bill and the progress of the Legislative Council's scrutiny of the Public Health and Municipal Services (Amendment) Bill 2008 ("Amendment Bill").

16. The FHB informed the RTF that –
 - (a) The proposals under the Food Safety Bill were generally supported by both the public and the trade;

 - (b) The Food Safety Bill involved many complex legal issues and required further liaison with the trade on the operational details. Some key issues which required further consideration included the definition of distributors, categorization of food types, exemption from registration, registration details and record keeping;

 - (c) The Administration was now working on the details of the Food Safety Bill with regard to the results of the public consultation. In order to have a better understanding of the views of the trade and whether improvements could be made to the details of the Bill having regard to the existing trade practice, the FHB, with the assistance of the Economic Analysis and Business Facilitation Unit, had appointed a consultant to conduct a Business Impact Assessment (BIA) to study the implications of the proposal on the trade. The study would take some four months to complete. The Administration would report the findings and recommendations of the BIA to the RTF in due course; and

 - (d) In view of immense public concerns about the recent incident of detecting melamine in milk and dairy products, the Administration had expedited work on the part of administrative orders to prohibit the import and supply of food and to order a recall of the food concerned in the Food Safety Bill and proposed to urgently amend the Public Health and Municipal Services Ordinance (Cap 132) accordingly, ahead of the introduction of the Food Safety Bill. The Amendment Bill was being scrutinised by a Bills Committee of the Legislative Council.

17. The RTF urged the Administration to consult the trade and other relevant business stakeholders, and give due regard to the findings and recommendations of the BIA in refining the details of the Bill, with a view to reducing the trade's compliance costs and administrative burden.

18. Though the Amendment Bill provided for a statutory compensation mechanism, the trade anticipated that it would be very difficult for an aggrieved person to establish that the Director of Food and Environmental Hygiene had made an order without reasonable grounds. The trade considered that compensation should be provided to innocent traders who had suffered loss from the Administration's orders made under the Amendment Bill.

19. The FHB explained that the food trade had the responsibility to ensure that the food they supplied was safe and fit for human consumption. They also had the responsibility to stop supplying problem food to the market and recall food that had already been supplied to protect consumers' health. The Administration had made reference to a number of overseas legislation in proposing the compensation mechanism. Only in the Australian legislation could the Government find provisions relating to compensation and in that legislation, compensation would only be granted if the authorities had acted unreasonably. The Administration would exercise its power to make orders under the Amendment Bill with care and in a restrictive manner. The Administration would also consider all relevant factors available before deciding whether there were reasonable grounds to make the order, including information or document provided by the food traders, if any, on the safety of the food. Under the Amendment Bill, any person bound by the order might within 28 days appeal to the Municipal Services Appeal Board. There was no provision in the Amendment Bill which restricted or eliminated judicial review or other civil claims. The Administration would issue a Code of Practice on the issue of orders under the Amendment Bill.

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

20. The Financial Services and Treasury Bureau has recently given its approval for the fee charging mechanism for the proposed composite licence. The FEHD is revising the draft drafting instructions accordingly for further comments by the Department of Justice.

Environmental levy scheme on plastic shopping bags

21. In preparation for the launch of the scheme, the Environmental Protection Department (EPD) has set up a Working Group on the Implementation of the Environmental Levy Scheme on Plastic Shopping Bags with the retail trade. The Working Group provides a forum to thrash out operational issues before and after the implementation of the scheme. The Working Group has so far held two meetings.

22. Separately, the Legislative Council has formed a Subcommittee to vet the Product Eco-responsibility (Plastic Shopping Bags) Regulation (“Regulation”) in detail. Subject to the approval of the Legislative Council on the Regulation, the Administration plans to commence the scheme in mid-2009.

23. The RTF appreciated that the Administration had taken into account the views of the trade in drafting the Regulation and introduced certain trade facilitation measures (e.g. minimising the information required for registration, adopting an exemption mechanism that did not require segregation of retail floor area, dispensing with the requirement of physical stock-taking of plastic shopping bags, extending the time allowed for submission of quarterly returns and payments, etc.). However, the RTF noted that some implementation details such as the commencement date of the scheme and the arrangement for third party operation had to be further sorted out.

24. In response to the Subcommittee’s invitation for deputations to relevant stakeholders, including the retail trade, the RTF made a written submission on 23 February 2009, suggesting that further consideration be given to the following issues in the Subcommittee’s scrutiny of the Regulation and in the Administration’s finalisation of the implementation plan –

- (a) to further review and refine the proposed arrangement for third party operation with the trade, particularly the trade’s concern that the requirement of “operating under a separate business registration at the location in question” was not strictly in line with the current trade practice;

- (b) the Administration should allow sufficient lead time for the trade's preparatory work such as IT system upgrades, review of internal operations, and briefing/training for staff, and provide a time line on key tasks in preparation for the scheme;
- (c) the Administration should establish clear key performance indicators to measure the effectiveness of the first phase of the scheme and map out concrete plans to extend the scheme; and
- (d) the Administration should also re-visit the issue of reimbursement of administrative cost to the trade as part of the review of the scheme one year after implementation.

25. Meanwhile, the EPD has undertaken to continue its collaboration with the trade through the Working Group for an early launch of the levy scheme.

Way forward

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

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