

**Twenty-seventh Meeting of  
the Business Facilitation Advisory Committee**

***Agenda Item 5(a) : Report on the work of the  
Wholesale and Retail Task Force***

**Purpose**

This paper reports on the work of the Wholesale and Retail Task Force (WRTF) since the last Business Facilitation Advisory Committee meeting held on 23 July 2014.

**Work progress of WRTF**

***Update on the progress of registration of proprietary Chinese medicines –  
September 2014***

2. The Department of Health (DH) has briefed WRTF on the progress of the registration of proprietary Chinese medicines (pCm) by the Chinese Medicines Board (CMB). It has been noted that the success rate of formal registration is only 3% and that there are still about 8,200 transitional registrations (HKP) not yet changed to formal registration. DH has explained that the application process is complex and as many registrants are SMEs, ample time has to be given to them to submit documents in order to fulfill the registration requirements. As long as the products are registered as HKP, they can still legally be sold on the market.

3. DH has introduced the following trade facilitation measures for processing transitional registration of pCm to formal registration –

- the deadline for the submission of the certificate of analysis and general stability test report has been extended from 30 June 2013 to 30 June 2015. Beyond that, the registrants may need to provide justifications for failing to meet the extended deadline and CMB will assess each case independently on its own merit to see if more time should be given;

- the product efficacy documents written by researchers or owners of the prescriptions, other than professionals, will also be accepted;
- the technical requirements of the product quality documents have been adjusted such that conditional approval for formal registration may be given provided that the specified conditions are met;
- when there is a change in the manufacturer of a pCm, the certificate of analysis of the product manufactured by the previous manufacturer may be provisionally accepted as a valid certificate of the new manufacturer provided that the specified conditions are met; and
- seminars have been organized to explain to the trade the technical aspects of the requirements with a view to helping them pass the tests.

4. DH has also clarified with WRTF that it is an international trend to license external re-packaging as a manufacturing activity. In Hong Kong, a manufacturer licence is mandatory for the external re-packaging of western medicines since 2013; however due to the historical background of pCm, a manufacturer licence is preferred but not mandatory for the external re-packaging of pCm at this juncture.

5. WRTF notes that for public safety, it is a standard requirement in both western medicines and the Mainland for the applicants to conduct necessary stability tests when the tablet coating is changed from sugar coating to polymer coating. Since the change to polymer coating is becoming a trend, DH has advised that CMB is considering whether a simpler testing method could be adopted in order to reduce the compliance cost of the trade.

6. WRTF appreciates DH's efforts in facilitating the trade and will continue to keep in view the progress of registration of pCm.

### ***Implementation of the Pesticide Residues in Food Regulation***

7. The Centre for Food Safety (CFS) of the Food and Environmental Hygiene Department has briefed WRTF on the implementation of the Pesticide Residues in Food Regulation (the Regulation) since 1 August 2014 and the supply of vegetables (particularly spinach, leaf mustard, green string beans and white string beans) in Hong Kong.

8. To ensure successful implementation of the Regulation, CFS has introduced the following trade facilitation measures –

- A channel is in place to assist the trade to submit proposals for addition/revision to the existing pesticide standards and to propose new exempted pesticides;
- To prepare the trade during the 2-year grace period, briefings and meetings have been organized for the trade and other interested stakeholders, including local traders as well as inspection, and quarantine authorities and food exporters in the Mainland;
- Three sets of guidelines have been issued to assist the trade on the interpretation of MRLs/EMRLs in the Regulation, use of the Codex's food classification to identify the appropriate pesticide residue limits, and submission of proposals for addition/revision to the existing pesticide standards and to propose new exempted pesticides;
- An on-line searchable database “Hong Kong Pesticide MRL Database” has been launched to assist the trade and public in finding relevant pesticide standards. The search function of the database will be enhanced to enable using both pesticide and food name as search keys; and
- Technical meetings and workshops on pesticide residues testing have been conducted for the local testing services sector to facilitate them to develop and equip themselves with the relevant testing techniques.

9. WRTF welcomes CFS' efforts in facilitating the trade.

***Update on the proposed import control of poultry eggs***

10. WRTF notes the progress update of the Food and Health Bureau (FHB) on the proposal to control the import of poultry eggs. Members urge the Government to ensure that the proposed regulation will cater for the different practices in all the egg-supply jurisdictions such that the supply of eggs to Hong Kong and the choices of eggs to consumers will not be affected. WRTF's views have been passed to FHB for consideration.

## **Way forward**

11. Members are invited to note the work progress of WRTF. The Task Force will continue to monitor the development of the above issues.

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