### For information on 25 January 2019

### Legislative Council Panel on Health Services and Panel on Commerce and Industry

## Joint Subcommittee on Issues Relating to the Regulation of Devices and Development of Beauty Industry

Regulatory and Support measures relevant to the Beauty Industry

#### **Purpose**

This paper outlines the Government's regulatory and support measures relevant to the beauty industry.

### **Regulation of Medical Devices**

- 2. The term "medical devices" generally refers to any instrument, apparatus or appliance that is used for diagnosis, treatment or monitoring of diseases and injuries. It covers devices that are used for the purpose of investigation, replacement, modification or support of the anatomy or physiological process of the human body. In defining the term, the Department of Health ("DH") has made reference to the definition of "medical device" as recommended by the Global Harmonization Task Force ("GHTF") (now the International Medical Device Regulators Forum ("IMDRF"))<sup>1</sup>.
- 3. To protect public health while ensuring our community's continued access to the benefits of new technologies, the Government proposes to introduce a statutory regime for regulation of medical devices. We last briefed the Legislative Council Panel on Health Services on 16 July 2018 on the latest

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Global Harmonization Task Force ("GHTF") was formed in 1992 to harmonise the standards and principles for the regulation of medical devices. In 2011, GHTF was disbanded, and a new regulator-led group known as International Medical Device Regulators Forum ("IMDRF") was formed to build on the foundational work of GHTF and aims to accelerate international medical device regulatory harmonisation and convergence.

development on the proposed regulatory regime (vide LC Paper No. CB(2)1787/17-18(03)).

- 4. In gist, the proposed regulatory framework adopts a risk-based approach whereby the level of control would be proportionate to the degree of risk classified for medical devices according to the recommended classification scheme of the IMDRF. It comprises pre-market control to ensure medical devices conform with the requirements on safety, quality, performance and efficacy before allowing them to be placed on the market<sup>2</sup>; and post-market control to enable swift control measures against defective or unsafe medical devices<sup>3</sup>.
- 5. Taking into account the feedback from stakeholders during the consultation, the current proposal would focus on pre-market control and post-market control and would not include use control of specified medical devices (i.e. not to restrict the use of specific types of medical devices to users with certain qualifications). To allow the supply and use of medical devices falling short of the registration requirements but still complying with basic listing requirements set by the DH, a five-year transitional "listing mechanism" will be introduced under the proposed regulatory regime. The target is to introduce the Medical Devices Bill to the Legislative Council in the current legislative session.

### Funding support for the development of small and medium enterprises in Hong Kong including those in the beauty industry

6. It has been the Government's policy to provide a favourable business environment for and render appropriate support to various trade and industries so that they can build on their respective strengths and grow. The Government administers various funding schemes to provide support to Hong Kong enterprises, in particular small and medium enterprises ("SMEs"). Among the funding schemes, the Trade and Industrial Organisation Support Fund provides financial support to non-profit distributing organisations to implement projects

Post-market control refers to the duties of traders of medical devices in Hong Kong to ensure the safety of medical devices supplied in the market, including maintaining records of supply, reporting adverse incidents associated with the medical devices and investigation results, implementing remedial measures to the satisfaction of DH, etc.

Pre-market control comprises registration or listing of medical devices, and registration and licensing of traders of medical devices in Hong Kong.

which aim at enhancing the competitiveness of Hong Kong enterprises in general or in specific sectors. Fundable activities include seminars, workshops, conferences, exhibitions, research studies, award schemes, codes of best practices, databases, service centres, support facilities and technology demonstrations, etc.

7. In addition, other Government funding schemes, including the Dedicated Fund on Branding, Upgrading and Domestic Sales, the SME Export Marketing Fund, the SME Loan Guarantee Scheme, as well as the special concessionary measures under the SME Financing Guarantee Scheme, provide support for Hong Kong enterprises in exploring export markets, obtaining finance and enhancing their overall competitiveness. Organisations and individual enterprises in the beauty industry have been using the above schemes in the past to apply for financial support to undertake projects to enhance the professional quality of the industry, strengthen competitiveness, or explore markets outside of Hong Kong. We welcome the beauty industry to make good use of the relevant funding schemes.

### **Development of Qualifications Framework for the beauty industry**

- 8. The Qualifications Framework ("QF") is a voluntary system that defines clear and objective standards applicable to qualifications in the academic, vocational, professional, as well as continuing education sectors. The objective of establishing QF is to promote lifelong learning and establish qualifications pathways for progression in learning.
- 9. Under the QF, Industry Training Advisory Committees ("ITACs")<sup>4</sup> are set up to serve as a platform for stakeholders to implement the QF and to exchange views on the training needs and manpower development of the respective industries. The Beauty ITAC was set up in 2006, and was merged with the Hairdressing ITAC to become the Beauty and Hairdressing ("B&H") ITAC in 2015. The B&H ITAC comprises representatives of employers, employees, trade associations, professional bodies and trade unions of the beauty and hairdressing industries.
- 10. The B&H ITAC has developed 239 beauty-related Units of Competency ("UoCs") under the Specification of Competency Standards

<sup>&</sup>lt;sup>4</sup> At present, we have set up 22 ITACs for implementation of the QF.

("SCS") to set out the skills, knowledge and competency standards required of the practitioners to perform various job functions in the beauty industry effectively. These UoCs are distributed in nine functional areas (namely Make-up; Nail, Hand and Foot Care; Health Care; Beauty Care; Body Care; Beauty Education and Training; Customer Services and Communication; Marketing and Sales; and Operation Management), ranging from QF levels 1 – 6<sup>5</sup>.

- 11. At present, there are more than 250 learning programmes in the beauty industry operated by over 60 operators (ranging from QF levels 1-5) which are recognised under QF and registered on the Qualifications Register ("QR"). Among these learning programmes, about 100 of them are SCS-based<sup>6</sup>.
- 12. QF enables formal recognition of the skills, knowledge and relevant experience acquired by practitioners in the workplace through the Recognition of Prior Learning ("RPL") mechanism. RPL for the beauty industry was launched in 2014. 56 RPL qualifications covering the nine functional areas for the beauty industry have been developed, ranging from QF levels 1 to 4. More than 1 800 applications from practitioners in the beauty industry seeking assessment of their qualifications under the RPL mechanism were processed.
- 13. The Government established the QF Fund in 2014 to support initiatives for the sustainable development and implementation of the QF. "Designated Support Schemes for QF" under the QF Fund not only provides subsidies to programme operators (including programme accreditation fees, fees for developing SCS-based programmes, QR registration and hosting fees, etc.), but also full reimbursement of the RPL assessment fees to practitioners. Programme operators and practitioners in the beauty industry can also benefit from the above initiatives.

# Training courses organised by the Employees Retraining Board ("ERB") for the beauty sector

<sup>&</sup>lt;sup>5</sup> The QF is a seven-level hierarchy. Each QF-recognised qualification is assigned a QF level in accordance with the outcome standards (knowledge and skills assessable and attainable) expected of the qualification. QF level 7 is the highest while QF level 1 is the lowest.

<sup>&</sup>lt;sup>6</sup> SCS-based learning programme means that the majority (over 60%) of the learning content of the course are drawn from SCS.

<sup>&</sup>lt;sup>7</sup> Examples of RPL qualifications are Statement of Attainment in Aromatherapy (Level 2), Statement of Attainment in Beauty Education and Training (Level 4), Statement of Attainment in Body Painting (Level 4), etc.

- 14. The ERB, an independent statutory body<sup>8</sup>, provides market-driven and employment-oriented training courses and services to improve the employability of local workers<sup>9</sup> to join or rejoin the employment market. Amongst the around 700 training courses straddling 28 industries currently offered by the ERB, 53 training courses are under the industries of "beauty therapy" or "hairdressing", of which 7 are full-time placement-tied courses and 46 are part-time "Skills Upgrading Scheme Plus" courses. Unemployed graduates of placement-tied courses will be offered with placement services for up to six months. In the financial year of 2017-18, a total of 7 210 trainees completed the beauty therapy or hairdressing courses by the ERB.
- 15. In general, the ERB will consult its 19 Industry Consultative Network (including the one for beauty therapy and hairdressing industries) to ascertain the employment opportunities of a particular industry or occupation and the need for developing related training courses. In the event that individual employers or business associations of the beauty industry can provide sufficient job vacancies and attractive terms of employment, they may approach the ERB regarding the development of suitable training courses.

### **Advice Sought**

16. Members are invited to note the content of the paper.

Food and Health Bureau
Commerce and Economic Development Bureau
Education Bureau
Labour and Welfare Bureau
Department of Health
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<sup>&</sup>lt;sup>8</sup> The Labour and Welfare Bureau is the housekeeping bureau for the training services by ERB.

<sup>&</sup>lt;sup>9</sup> ERB's service targets are local residents aged 15 or above with education attainment at sub-degree level or below.