Proposed Regulatory Framework for Medical Devices – Deputation Meeting held by Legislative Council Panel on Health Services, 13 Feb 2017

Views submitted by the College of Surgeons of Hong Kong

1. The proposed regulatory framework is welcomed and the College of Surgeons of Hong Kong agrees with the approach of the proposed regulation.

2. The proposal formalizes and improves upon the existing Medical Device Administration Control System into a more comprehensive statutory regime for the regulation of medical devices with pre- and post-market control measures. In addition, it establishes a mechanism for the control of usage of devices also being employed for cosmetic applications, which currently is being operated by a great number of non-registered healthcare professionals. These measures should be conducive to public safety.

3. On use control concerning devices also being used for cosmetic purposes, the categorical assignment of the researched medical devices in Table 2 (Recommended Medical Device Use Control Categories) of Annex II of the proposal, i.e. the Executive Summary of the Report of the Study on the Control of Use of Selected Medical Devices in Hong Kong, is built upon a reasoned and researched foundational basis. Flexibility, nevertheless, cannot be over-emphasized. Some device types in Category III or IV may arguably be put under Category II or III because different makes and models of the same type of medical device can still vary in clinical risks and requirements of knowledge and skills. The ultimate safety of any precise piece of device is accordingly dependent on its particular specifications and the operators. It is therefore imperative that the details of the use control category allocation be reviewed before the final implementation of the legislation. As already in the proposal, there must be a mechanism for regular re-examination and update of this table.

4. We want to emphasize that the categorization of the devices should be adjusted on an individual basis. Since the energy and power delivered can vary, devices can potentially cause harm to patients if not controlled and delivered by qualified person according to set guidelines.