Submission of the Consumer Council to the Legco Panel on Health Services on Regulation of Medical Devices

1. Introduction of Regulatory System on Medical Devices

1.1 The Consumer Council supports the implementation of a regulatory system on medical devices for the reasons below:

1.2 Over the years, the Consumer Council has tested products related to health and medical services and found safety or quality problems in some. For example, in the Council's tests, problems were identified in respect of inaccuracy and inconsistency in the performance of blood glucose meters and blood pressure monitors. As to contraceptive devices which are proposed in Appendix A of the consultation document to be listed under medical devices, some condom samples failed in regard water leakage and breakage resistance in various tests performed by the Council.

1.3 At present there is no specific legislation to regulate the importation or sale of medical devices in Hong Kong except for those involving pharmaceutical products or radioactive substances. If other jurisdictions close to Hong Kong have regulatory systems for medical devices while we do not, Hong Kong could become the easy dumping ground of poor quality or dangerous medical devices.

1.4 Consumers in Hong Kong have higher health awareness after the SARS epidemic as evidenced by the increasing number of consumer enquiries and requests for testing of medical and health-related products e.g. face-masks and personal air purifiers. On the other hand, advances in technology have made medical devices more user-friendly and easily available to consumers. Yet the safety and quality of these products have great bearing on those who use them so they should not be

taken lightly as purely consumer goods. Regulation should be in place for monitoring purpose so that consumers will be protected.

2. Principles of Regulation

2.1 The Council agrees to the classification of medical devices into four classes according to the degree of risk along the recommendations made by the Global Harmonization Task Force ("GHTF"). The Council also supports that the level of regulatory control should increase with increasing degree of risk.

3. Scope of Control

3.1 Pre-market Control

3.1.1 The Council notes that to shorten the time taken for assessment, one of the registration options proposed is for the applicants to submit evidences of product safety, effectiveness and quality if their products have already been approved for marketing in specified GHTF founding member countries or regions. The Council agrees that experience gained in GHTF founding member countries will serve as good reference for the prospective regulatory system in Hong Kong. However, the Council reckons that it will be vital for the regulatory authority to ensure that in such cases the medical devices to be sold in Hong Kong would be the same, in terms of quality, safety, design and method of use etc, to those already available in GHTF founding member countries.

3.1.2 It is understood that monitoring the compliance of these equipments would pose a heavy burden to the Authority. The Council therefore suggests that the applicants in respect of such medical devices should be required to make declaration during the registration process to the effect that products under application are the same as those which were approved for marketing in GHTF founding member countries. Hence the onus of proof lies with the applicants and it will ease the burden of the regulatory authority in proving the authenticity of the submitted evidence.

However, some manufacturers may produce different versions of the same medical device to meet the needs of consumers in different geographic locations (such as products manufactured for the Asian market). Different versions should be registered separately so that consumers can purchase the versions that best suit their needs and yet still have the assurance afforded by registration of the particular versions with distinctive features.

3.1.3 Classification of medical devices should be subject to review on a regular basis. Both suppliers and consumers / end users should have the right to appeal in respect of the classification.

3.2 Control in the use and operation of selected high risk medical devices

3.2.1 The Council is concerned with unnecessary harm and complications arising from the improper use of medical devices. In the absence of control mechanism, persons without proper training and qualifications may also use devices intended for use by specified personnel. An example is the use of medical lasers or intense pulse light (IPL) equipment by unqualified personnels in beauty parlours.

3.2.2 According to statistics of the Consumer Council, consumer complaints related to cosmetic services and in particular IPL treatments are on a significant rise. Complaints involving IPL treatments jumped from only one each in 2001 and 2002 to 26 complaints in 2003. As regards laser treatments, there were 14 complaints in 2003. Of the two categories of cases, 19 and 8 of the complainants respectively claimed to suffer from side effects or other complications after cosmetic treatment.

3.2.3 The Council supports limiting the use or operation of higher risk medical devices, such as laser equipments intended for medical therapy, to specified personnel.

3.3 Post-market Control

3.3.1 For high risk level devices such as those to be classified as classes III and IV, the

suppliers should be required to provide sufficient training to end users, to take precautionary measures to minimize potential health hazards associated with use of the devices, and to collect data on their performance and safety .

3.3.2 In the absence of a compulsory system of reporting adverse incidents, local health facilities rely heavily on overseas official information sources. To enable timely intervention to be made, mandatory reporting of serious adverse incidents is essential to ensure the safe use of the devices. The Council recommends that a local hotline be set up for case reporting to ensure that an adverse incident reporting and surveillance system can be in place and operate smoothly, so that remedial actions can be taken in a timely manner.

4. Time Frame

4.1 The Council notes that the control system will start with the listing of high risk (Class IV) medical devices, their importers and manufacturers in 2004. After review and evaluation, listing of Class III and Class II devices etc will follow in stages.

4.2 While the Council understands that the regulatory authority needs to prioritize issues by their urgency, it cannot ignore the potential danger associated with the current situation where there are no controls on certain medical devices like laser equipment or the qualification of the operators. From the proposed time-table, it is envisaged that the operators of laser equipment will not be regulated before 2006. This would mean a very long time before consumers get their proper protection over the use of beauty services rendered by means of laser equipment. The Council submits that this may have implication on medical costs necessary for follow-up and urges the government to speed up its control on medical devices of increasing prevalence and on the qualification of those operating them.

The Consumer Council
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