中華人民共和國香港特別行政區政府總部食物及衞生局
Food and Health Bureau, Government Secretariat
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

Our Ref : FH CR 6/3921/09
Your Ref : CB2/PL/HS

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Ms Maisie LAM
Clerk to Panel
Legislative Council Panel on Health Services
Legislative Council Complex
1 Legislative Council Road
Central, Hong Kong

Dear Ms Lam,

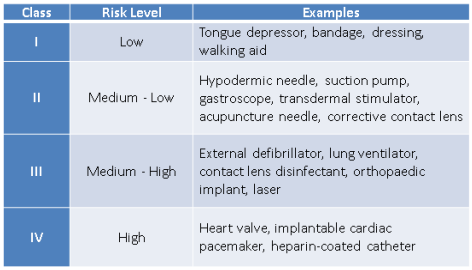
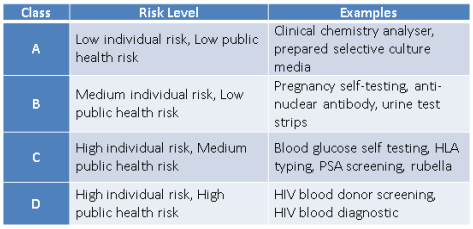
Proposed Regulatory Framework for Medical Devices

During the discussion on the captioned subject at the meeting of the Legislative Council ("LegCo") Panel on Health Services held on 16 January 2017, Members requested the Administration to provide supplementary information. Our response is set out in the ensuing paragraphs.

2. According to the discussion paper presented by the Administration (LC Paper No. CB(2) 545/16-17(01))("Paper"), the initial proposed statutory regulatory regime comprised three main areas, including "pre-market control", "post-market control" and "use control". Proposed regulatory framework and classification rules / levels of control outlined in the Paper are summarized in the table below -

<table>
<tr><th>Para. No. at the Paper</th><th>Proposed regulatory framework outlined in the Paper</th><th>Overview of proposed regulation outlined in the Paper</th><th>Classification rules / Levels of control proposed in the Paper</th></tr>
<tr><td>18-27</td><td>Pre-market control
(applies to <u>all</u> medical devices)

(Including:
● Registration of medical devices by model
● Registration / Licensing of traders - including local manufacturers, authorised representatives, importers and distributors
● Recognition of conformity assessment bodies
● Appeal mechanism
● Labelling requirements and control over advertisements)</td><td>Following the risk-based approach, the Administration will not impose registration requirement on Class I general medical devices and Class A in vitro diagnostic medical devices (“IVDMDs”) due the low risk posed.

For Class II-IV general medical devices and Class B-D IVDMDs, they are required to be registered with the Department of Health (“DH”) before they can be supplied to the market.</td><td rowspan="2">According to the rules of the Global Harmonization Task Force, general medical devices are classified into four classes based on their risks (e.g. invasiveness, length of retention in body, location of implant, etc.) -
 
For IVDMDs, they are also classified into four classes according to another set of classification rules with respect to their risks to individual users and the public as follows –
  </td></tr>
<tr><td>28-29</td><td>Post-market control
● Post-market surveillance system and adverse incident reporting
(applies to <u>all</u> medical devices)</td><td>Traders including authorised representatives, local manufacturers, importers and distributors of medical devices must be registered with or have obtained a licence from the DH before they can supply any medical devices in Hong Kong.</td></tr>
<tr><td>30</td><td>Use control
(only applies to <u>specific</u> medical devices)</td><td>The Administration will adopt a risk-based approach to impose use control on specific medical devices. In this regard, we will not impose use control on medical devices with low risk in their use. In addition, the proposed</td><td>The external consultant commissioned by the Government recommended that the 20 types of specified medical devices should undergo use control assessment according to its clinical risk, regulatory requirements, knowledge and skills; and be assigned use</td></tr>
</table>

		regulatory framework will not impose control on use of medical devices by the registered healthcare professionals as their practice will be subject to the respective professional code of conduct. The proposed regulatory framework of use control will **focus on specific medical devices which are often used by persons other than registered healthcare professionals for non-medical purposes**, and the use of these devices may pose a high risk of serious injury or harm to the public if the users have not undergone proper training and acquired appropriate qualifications.	control category with reference to the user qualification requirements. Making reference to the consultant's recommendation, it is proposed in the Paper that some medical devices which have undergone the above assessment should be regulated under two levels of use control – Category (a) - users must be supervised on site by a registered medical practitioner Category (b) - users must be supervised on site by a registered medical practitioner or be persons who have successfully completed the relevant training programme as recognised by the Government

3. However, the Administration received views and concerns from different sectors regarding the use control of specified medical devices over the past few months. We understand that consensus over "use control" will not be reached any time soon. As the general public expects that the "pre-market control" and the "post-market control" for medical devices can be introduced as soon as practicable, the Administration will first focus efforts to take forward the legislative work on the above two areas. After we have made substantive progress on the legislative proposals for "pre-market control" and "post-market control", we will revisit and consider the issues of use control categorization of specified medical devices and related matters with regard to the latest situation. Therefore, when drafting the current bill on medical devices, we will not include the part related to "use control".

Yours sincerely,

(Miss Yvonne TAM)
for Secretary for Food and Health