Proposed Regulatory Framework for Medical Devices
規管醫療儀器的建議架構

Food and Health Bureau
食物及衞生局
Department of Health
衞生署

16 July 2018
二零一八年七月十六日

衞生署
Department of Health

Original Regulatory Proposal
原來的規管建議

衞生署
Department of Health

- **Pre-market Control**
  推出市面前的管制
  - To ensure medical devices conform with the requirements on safety, quality, performance and efficacy before allowing them to be placed on the market
    在容許醫療儀器推出市面前，確保醫療儀器符合有關安全、品質、性能和效能的規定
- **Post-market Control**
  推出市面後的管制
  - To enable swift control measures against defective or unsafe medical devices
    對有問題或不安全的醫療儀器迅速施加管制措施
- **Use Control**
  使用的管制
  - To restrict the use of specific medical devices to specified personnel
    限制特定類別的人員使用某些醫療儀器

Refined Regulatory Proposal
修訂的規管建議

衞生署 Department of Health

- **Key features**
  主要部份
  - Pre-market and Post-market Control
    推出市面前及推出市面後的管制
  - **Not including "Use Control"**
    不包括「使用管制」
  - Adjusting **documentary evidence for Registration** of medical devices
    適度地調整**醫療儀器註冊所需的證明文件**
  - Introducing **a Transitional Listing System** for medical devices
    實施**過渡性質的醫療儀器「表列制度」**

1. Pre-market and Post-market Control
推出市面前及推出市面後的管制

衞生署 Department of Health

- **Pre-market Control 推出市面前的管制**
  - Product registration (except for low risk devices (e.g. bandage) and exempted devices) or listing
    產品註冊(除低風險儀器(如繃帶)及獲豁免儀器外)或表列
  - Trader registration and licensing (authorised representatives (AR), local manufacturers, importers and distributors)
    貿易商註冊及發牌 (授權代表、本地製造商、進口商及分銷商)
  - Validity period for device registration/listing extends to 5 years
    儀器註冊/表列有效期延至5年
- **Post-market Control 推出市面後的管制**
  - Post-market surveillance system (e.g. product recall)
    推出市場後的監察系統(如產品回收)
  - Adverse incident reporting
    醫療事故呈報
- Supply of medical devices manufactured / imported **before the commencement** of the proposed legislation **will not be affected until the end of the grace period**
  在建議法例**生效日期前**已製造/進口的醫療儀器，其供應於**寬限期完結前將不受影響**

2. Not including "Use Control"
不包括「使用管制」

衞生署
Department of Health

- The proposed regulatory regime **will not include "Use Control" of specific medical devices**
  建議的規管架構**將不會包括特定醫療儀器的「使用管制」**

- Other key jurisdictions: Use control of medical devices regulated by means other than legislation for medical devices
  其他主要司法管轄區：透過醫療儀器條例以外途徑規管醫療儀器的使用

3. Adjusting documentary evidence for Registration
調整醫療儀器註冊所需的證明文件

衞生署
Department of Health

- **Original Proposal**
  原來建議
  - Marketing approvals from 5 Global Harmonisation Task Force (GHTF) founding members: Australia, Canada, EU, Japan and the US accepted; or
    接受由五個全球協調醫療儀器規管專責小組(GHTF)創始成員國監管機構發出銷售核准證明：澳洲、加拿大、歐盟、日本和美國；或
  - Conformity Assessment Bodies (CAB) certificates accepted
    接受認證評核機構發出的認證評核證書

- **Refined Proposal**
  修訂建議
  - In addition to the above, accept marketing approvals from Mainland China and South Korea in the initial phase (no CAB certificate is required)
    除了上述文件，首階段計劃接受內地及南韓的銷售核准證明 (無需認證評核證書)

4. Transitional Listing System
過渡性質的「表列制度」

- Medical devices falling short of registration requirements can be “listed” under the **“Listing System”**

  容許未符合註冊規定的醫療儀器可於**「表列制度」**下「表列」

  - Active Class II or III non-invasive general medical device which may be used for modifying the anatomy or physiological process of skin of a person to enhance physical appearance

    第II或III級的非入侵性有源的一般醫療儀器，用以改變個人皮膚的結構或生理過程，以保持、修復或改善外觀

  - Used by beauty industry or members of the public for self-use

    供美容業或市民自用的儀器

- **Limit the transitional period to five years** (i.e. beyond the five-year transitional window, Government will not allow new applications for devices to be listed)

  為表列制度設定五年的過渡期 (即為期五年的過渡期後，政府將不會接受新的醫療儀器表列申請)

- End -

-完 -

衞生署
Department of Health