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Regulation of Medical Devices
醫療儀器的規管

Food and Health Bureau
Department of Health
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衞生署

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Regulation of Medical Devices
醫療儀器的規管

- Purpose of the regulation of medical devices is to **safeguard public health** by regulating the **supply** of medical devices in Hong Kong, while **ensuring continued access to the benefits of new technology**

  醫療儀器規管旨在透過規管醫療儀器在香港的**供應**以**保障公共衞生**，並確保社會**持續獲得新科技所帶來的好處**。

- Proposed regulatory framework adopts **International Medical Device Regulators Forum (IMDRF)** (or the former Global Harmonisation Task Force (GHTF))'s recommendations

  建議規管架構採納**國際醫療器械監管機構論壇 (IMDRF)** (或前身為全球協調醫療儀器規管專責小組 (GHTF))的建議。

Definition of Medical Devices
醫療儀器的定義

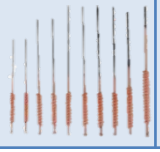
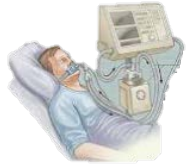
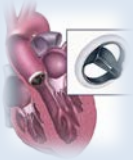
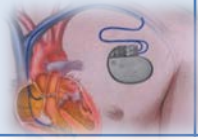
Any instrument, apparatus, implement, machine, appliance, implant, reagent for in-vitro use , software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for any one or more of the specific medical purpose(s) of:-
製造商擬用於人體作以下一項或多項特定醫療用途的任何器材、設備、工具、機器、器具、植入物、體外試劑或校準器、軟件、物料或其他類似或有關物品(無論是單獨或以組合形式使用)：

- diagnosis, prevention, monitoring, treatment or alleviation of disease; or
  診斷、預防、監察、治療或減輕疾病；或
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury; or
  診斷、監察、治療、減輕傷勢或為補償因傷而受損的功能；或
- investigation, replacement, **modification, or support of the anatomy or a physiological process**; or
  檢驗、替補、**調節或維持身體結構或生理過程**；或
- supporting or sustaining life; or
  維持或延續生命；或
- control of conception; or
  控制受孕；或
- disinfection of medical devices; or
  消毒醫療儀器；或
- providing information by means of in vitro examination of specimens derived from the human body
  為從人體抽取的樣本進行體外檢驗或診斷，以提供資料作醫學用途；

AND
does not achieve its primary intended action in or on a human body by pharmacological, immunological or metabolic means, though its intended function may be assisted in by such means
及
而該等儀器並非透過藥物、免疫或新陳代謝的途徑在人體內或人體上達至主要的原擬作用，但可通過這些途徑助其發揮原擬功能。

Classification of Medical Devices
醫療儀器的分級

Examples on Classification of Medical Devices
醫療儀器分級的例子

Class 級別	Risk 風險級別	Examples 例子			
I	Low 低	Tongue depressor 壓舌板 	Bandage 繃帶 	Walking aid 助行器 	
II	Medium-Low 中-低	Acupuncture needle 針灸針 	Corrective contact lens 矯視性隱形眼鏡 	Blood pressure monitor 血壓計 	ESWT device 體外衝擊波儀器 
III	Medium-High 中-高	AED 體外除顫器 	Ventilator 肺部呼吸器 	HIFU 高强度聚焦超聲波儀器 	
IV	High 高	Artificial heart valve 人造心瓣 	Implantable pacemaker 植入式心臟起搏器 	Dermal filler 皮膚填充劑 	Breast implant 乳房植入物 

用於美容程序的醫療儀器(以上紅色字例子)只佔醫療儀器的一小部分。
Medical devices used in cosmetic procedures (examples in red) only constitute a small proportion of medical devices.

“Beauty Devices”
「美容儀器」

- “Beauty devices” refer to certain medical devices used in cosmetic procedures, which are used to **enhance physical appearance** through modification or support of the anatomy or a physiological process.

  「美容儀器」指一些用於美容程序的醫療儀器，而該儀器是透過調節或維持身體結構或生理過程達致**改善外觀**的目的。

Examples of “Beauty Devices”
「美容儀器」例子

「美容儀器」 “Beauty Device”	風險級別 Risk Class
Micro-needle 微針	Normally Class 1 or 2 (depends on single-use or not) 常見是 1 或 2 級 (取決於是否單次使用)
Extracorporeal shock wave therapy (ESWT) device 體外衝擊波儀器	Normally Class 2 常見是 2 級
Radiofrequency (RF) device 射頻儀器	Normally Class 2 or 3 常見是 2 或 3 級
Infrared (IR) device 紅外線儀器	Normally Class 2 or 3 常見是 2 或 3 級
Laser device 激光儀器	Normally Class 2 or 3 常見是 2 或 3 級
Intense pulsed light (IPL) device 强烈脈衝光儀器	Normally Class 3 常見是 3 級
High intensity focused ultrasound (HIFU) device 高强度聚焦超聲波儀器	Normally Class 3 常見是 3 級
Dermal filler 皮下填充劑	Normally Class 4 常見是 4 級
Breast implants 乳房植入物	Normally Class 4 常見是 4級

Medical Devices and “Beauty Devices”
醫療儀器 與「美容儀器」

	Medical Devices 醫療儀器	“Beauty Devices” 「美容儀器」
Technology **技術**	Application of medical technology 應用醫療技術	
Mechanism **原理**	Effect on human tissues and cells, through application of medical principles 透過應用醫學原理影響人體組織和細胞	
Risk **風險**	e.g. burn, scarring, permanent disfigurement and eye damage 例如：燒傷、留疤、永久毀容和眼睛受損	

Medical Devices and “Beauty Devices”
醫療儀器 與「美容儀器」

- Difficulties in differentiating Medical Devices and “Beauty Devices”

  區分醫療儀器和「美容儀器」的困難

By Energy Output Level 以輸出能量作區分	By Intended Purposes 以原擬用途作區分	By Intended Users 以原擬使用者作區分
• Energy output level is not used to define medical devices internationally 能量輸出水平並非國際間定義醫療儀器的準則 • For devices adopting same technology, there can be overlap in the range of energy output or the parameter may be similar 就同一技術類型的儀器而言，能量數值可能有重疊或相近的情況	• Medical devices are not limited to treating diseases 醫療儀器不限於只用作治療疾病的儀器 • Whether treatments based on medical principles to achieve cosmetic effects should be regarded as cosmetic procedures is controversial 基於醫學原理達至美容效果的療程是否只應被視作美容程序具爭議性	• Healthcare professionals are not necessarily the only users of medical devices. 醫療儀器並非只是原擬給醫療專業人員使用 • Cannot conclude that a device intended for use by beauty practitioners is not a medical device 不能因儀器原擬由美容從業者使用，便否定該儀器屬醫療儀器

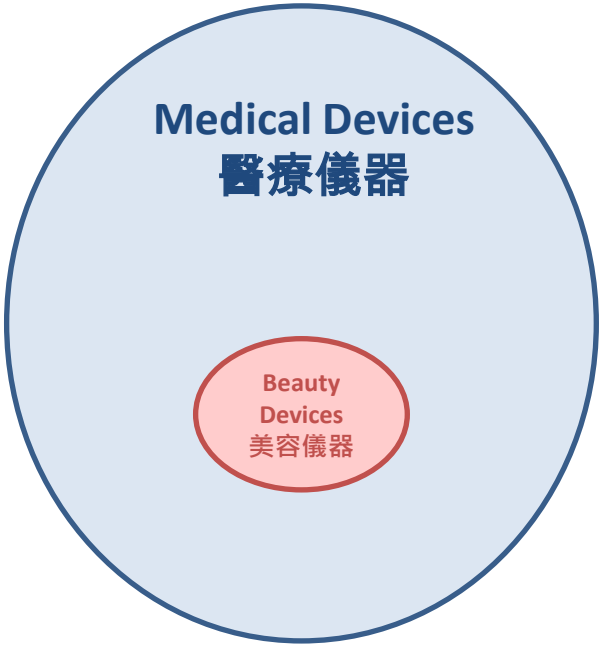
Regulation of "Beauty Devices"
「美容儀器」的規管

US 美國	EU 歐盟	Others 其他地方
• According to US FDA, even if products are marketed purely for cosmetic purposes, any intention to affect the structure or function of the body makes them drugs or medical devices 美國食品和藥物管理局明確表示，儘管產品出售作美容用途，如原擬影響身體結構或功能，均是藥物或醫療儀器 • US FDA warning letters issued to manufacturers and/or distributors of devices marketed for face lifting, lipolysis, dermabrasion and laser hair removal, as well as micro-needling device and dermal fillers illustrate that such devices are regulated under the medical devices regulation 美國食品和藥物管理局曾採取執法行動，向提升面部輪廓、脂肪分解、磨皮、激光脫毛等儀器、微針和皮下填充劑的製造商及分銷商發警告信，說明有關產品需受醫療儀器法例的規管	• The new EU Medical Devices Regulation covers certain devices intended for cosmetic purposes, including electromagnetic radiation emitting devices intended for skin rejuvenation and hair removal or other skin treatment (e.g. laser or IPL devices) and devices intended to be used to reduce, remove or destroy adipose tissue. 歐盟在新的醫療儀器條例申明，一些作美容用途的儀器，包括釋放電磁輻射以用於換膚和脫毛等皮膚療程的儀器(如激光及彩光儀器) 和減少、去除或破壞脂肪組織的儀器，須視作醫療儀器並須受該條例規管。	• Other countries, such as Canada and Singapore, their Medical Device Registries also include "beauty devices" registrations 其他國家，例如加拿大和新加坡，其醫療儀器註冊數據庫也包涵美容儀器的登記 • Places with regulatory regime of medical device in place include "beauty devices" meeting the definition of medical devices under the regime rather than regulating "beauty devices" separately. 在有醫療儀器法例的地方，符合醫療儀器定義的「美容儀器」都會如常按一般醫療儀器規管，並沒有將有關「美容儀器」分別處理

Regulation of “Beauty Devices”
「美容儀器」的規管

- Advanced jurisdictions such as Australia, Canada, the EU, the US, South Korea and the Mainland have included “beauty devices” meeting the definition of “medical devices” under their medical devices regulatory framework

  多個先進司法管轄區，如**澳洲、加拿大、歐盟、美國、南韓及內地**，都已把符合「醫療儀器」定義的**「美容儀器」納入其醫療儀器規管架構內**。



- No separate regulatory system for “beauty devices” identified and not aware of jurisdictions with regulatory regime of medical devices in place which do not regulate “beauty devices” as part of the regime

  未找到獨立的「美容儀器」規管制度，亦未見設有醫療儀器規管制度但不規管「美容儀器」的司法管轄區。

Latest Legislative Proposal
最新立法建議

Introduce pre-market and post-market controls first
先推行推出市面前及推出市面後的管制

Revisit at later stage
稍後階段重新研究

Proposed Regulatory Framework
建議的規管架構

Pre-market Control
推出市面前的管制

- 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

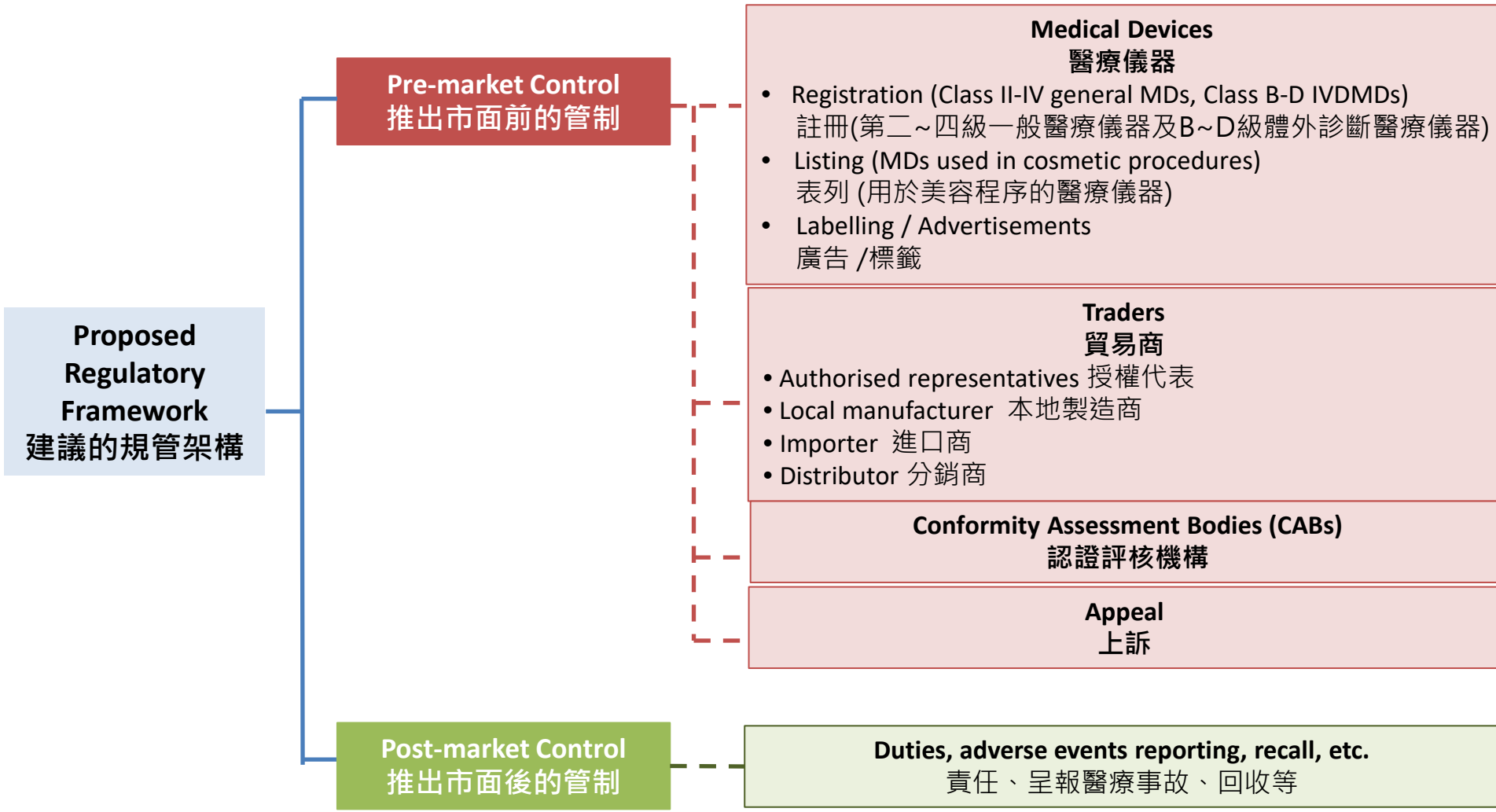
Post-market Control
推出市面後的管制

- 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

- Restrict the use of specific types of medical devices
  限制某些高風險醫療儀器的使用

Latest Legislative Proposal
最新立法建議



Refinements on Registration Requirements
醫療儀器註冊要求的修訂

		Previous Proposal 先前建議	Refined Proposal 修訂建議
Conformity Assessment 認證評核	**Route 1 (by CAB)** **路線 1 (由CAB 進行)**	CAB Certificate 認證評核證書	Unchanged 不變
	Route 2 (by DH) **路線 2 (由衞生署評核)**	● Documentary evidence demonstrating the safety and performance of the medical device (e.g. risk analysis report, clinical study) 證明醫療儀器安全及性能的文件(如風險分析報告、臨床評估) ● Marketing approvals from GHTF founding members GHTF 創始成員國的醫療儀器銷售核准證書	● Unchanged 不變 ● Marketing approvals from GHTF founding members + certain jurisdictions (e.g. South Korea & Mainland) GHTF 創始成員國 + 其他司法管轄區的醫療儀器銷售核准證書(例如南韓及內地)

Listing System
表列制度

Devices qualified as listed MDs **表列儀器的資格**	1. Class II or III non-invasive device and operated on a source of electrical energy 第二或第三級非入侵性並以電力驅動 2. For skin-related purposes 皮膚相關為目的 3. Intended to be used by general public 原擬供一般公眾使用
Requirements of listed MDs **表列儀器的要求**	1. Electrical Safety (IEC 60335) 電氣安全 (IEC 60335) 2. Labelling 標籤
Applicant **申請者**	Authorized Representative 授權代表
Renewal of listed device **表列儀器的延續**	Every 5 years 每 5 年
Transitional arrangement **過渡安排**	1. 5-year transitional period 5 年過渡期 2. Accept applications within the 5-year transition window, no new applications for listing will be accepted beyond the transitional window 於5年過渡期內接受准許申請，於5年過渡期後，不再接受任何新的准許申請

Transitional “Beauty Devices” Listing System
過渡性「美容儀器」的表列制度

- The Government believes that the transitional arrangement would allow the industry to migrate to and familiarise with the statutory registration regime, with a view to **raising the standard of “beauty devices” in Hong Kong in the long run.**

  政府相信這項過渡安排，可讓業界逐漸過渡至法定註冊制度並熟習這個制度，**長遠而言達至提升香港「美容儀器」的標準**。

Thank You

謝謝