出國報告（出國類別：參加國際會議）

2014 年 Medical Device and IVD Regulations in Asia Pacific 會議報告

服務機關：衛生福利部食品藥物管理署
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派赴國家：英國倫敦
出國期間：103 年 6 月 2 日–6 月 6 日
報告日期：103 年 7 月 24 日

摘要

本次亞洲區醫療器材暨體外診斷醫療器材法規研討會，主要是在討論亞洲區國家（包括：澳洲、紐西蘭、中國大陸、日本、韓國、新加坡、馬來西亞、印度、菲律賓、ASEAN）之最新法規的更新與各國差異，也有國際醫療器材法主管機關論壇（International Medical Device Regulatory Forum, IMDRF）與亞洲醫療器材法規調和組織（Asia Harmonization Working Party, ）各工作小組最新的法規調和情形。會議之主要討論內容包括：（1）各國最近醫療器材註冊、審查法規的更新、審查時間比較等；（2）各國醫療器材上市後管理的法規和執行情形；（3）國際醫療器材法規主管機關論壇之法規建議與亞洲區醫療器材法規調和組織最新動態；（4）業者成功取得各國上市許可案件經驗分享；（5）各國管理法規差異分析，送審資料的差異分析；（6）亞洲區醫療器材仿單標示要求與比較。我國於此次會議中除報告我國最新的醫療器材與體外診斷試劑管理法規更新與未來可能的法規變更，並報告最新的國際合作進度（FLASH UPDATE and insight on market approval requirements and expectations in Taiwan）。此外與其他國家或代施查核機構、認證機構代表討論很多亞洲區國家相關管理法規的要求與送審資料格式的差異，未來澳洲與紐西蘭主管機關將合併成ANZTPA（Australia and New Zealand Therapeutic Administration），在醫療器材上市前審查管理與上市後監視管理，也將一併整於 ANZTPA 管理架構下，在法規與實際執行上有分析與討論，我國將持續與其他國家醫療器材上市前審查與上市後法規管理調和，以增進我國醫療產品法規之國際交流，我國產品外銷與吸引國際醫療器材廠進駐我國。

關鍵詞：IMDRF、AHWP、體外診斷醫療器材（in vitro diagnostic device, IVD）、上市後監視（post market surveillance ＆vigilance）

目　次

壹、目的

本次會議是Informa Life Sciences第8次舉辦醫療器材暨體外診斷醫療器材之亞洲區國家法規交流研討會，衛生福利部食品藥物管理署醫療器材及化粧品組受邀派員演講「FLASH UPDATE and insight on market approval requirements and expectations in Taiwan」，報告我國最近醫療器材與體外診斷醫療器材之管理法規近況，包括上市前審查要件與國際法規調和情形，並報告我國與國際合作最新動態，同時了解亞洲區各國最新醫療器材與體外診斷醫療器材之法規：上市前審查/送審資料格式、臨床試驗與查核、上市後監控與變更管理、仿單格式與審查等，並與其他國家討論交流，期望藉由研討會，討論差異，尋求法規調和的提昇，加速產品流通國際市場與追蹤管理。本次參加會議之任務：

一、 報告我國醫療器材暨體外診斷醫療器材最新管理規定，去（102）年7月為配合行政院組織改造，衛生福利部成立後，食品藥物管理署也因此擴編，醫療器材與化粧品組之使命（捍衛全民健康、打造醫粧管理新時代、聰明管理創造多贏）、願景（健全法規管理體系、落實全生命週期風險管理、保護消費者安全、促進生醫產業發展）、核心價值（專業、創新、效率、服務）及對產品全生命週期管理的重心提昇（由過去：依法規為基礎專業審慎的審查 → 現在：建立積極全方位的輔導產業，以風險管理為審查原則，保護民眾使用醫療器材之效能與安全→未來：將強化產品的追蹤管理與產品流通的管理），最近及未來法規更新或產品上市前之查驗登記審查原則與要件、資料文件送審格式、審查流程時間、上市後產品監控機制（包括製造廠、廠商和政府的責任），最近國際合作動態等做一報告。

二、 了解亞洲區各國醫療器材法規管理之最新更新情形，藉由研討會的平台溝通、討論，分析各國之間的差異與管理重點，期能提昇我國與各

國之實質合作，朝向提昇審查時效、加速產品進入彼此國家與安全合作監控。

貳、過程

一、行程安排

日期	行程
103 年 6 月 2 日	啟程（長榮航空 BR67;桃園機場出發) 抵達英國倫敦
103 年 6 月 3 日	Day 1: China, Clinical requirements, Regulatory harmonization, Post market surveillance, adverse events and recall, Developing regulatory strategies, Medicals device software regulation
103 年 6 月 4 日	Day 2: Korea, ASEAN, Asia Pacific Workshop, **Taiwan**, IVD Registrations
103 年 6 月 5 日	Day 3: Japan, India, Experience exchange: worked examples, Labelling, Post approval change management, Australia & New Zealand, Electronic submission
103 年 6 月 5-6 日	回程

二、參加會議過程及會議內容

（一)第一天會議（**6** 月 **3** 日)：國際醫療器材法規論壇（**the International Medical Device Regulators Forum, IMDRF**）、亞洲區醫療器材法規調和組織（**Asia Harmonization Working Party, AHWP**）、中國大陸之情形，各國上市後管理法規比較、成功個案經驗分享與討論（議程詳參附件 **1**）

1. 中國大陸：原來的 SFDA（State Food and Drug Administration）提昇成 CFDA（China Food and Drug Administration），下面分別有 Provincial FDA, Municipal FDA 分層負責管理不同風險等級的醫療器材，目前的網站（ http://eng.sfda.gov.cn/WS03/CL0755/）。於中國大陸本地製造的醫療器材，只有高風險的 class 3 需送件至 CFDA 審核核發許可證，中等風險之 class 2 醫療器材則由 Provincial FDA 審核發許可證，低風險的 class 1 則授權由 Municipal FDA 權管。Class 1 之醫療器材，則不需審查，也不發證，只需向 Municipal FDA 報備（notification）即可。然而如果是輸入之醫療器材，則不論風險等級全部都必須檢送技術文件至 CFDA，經註冊核備或審核後方可輸入，且該欲輸入之醫療器材必須於原產國已經上市之產品。雖然目前中國大陸並未有海外查廠之實際案例，但是海外製造廠必須送邀請函予 CFDA，邀請其查廠，再由 CFDA 告知廠商，先送製造廠之品質系統文件資料予以審查。對於一個醫療器材可能由多個製造廠完成部分，最終成品僅在其中一個製造廠組裝完成或完成最後關鍵性製程，則每一製造廠與廠址都需列於許可證上，且標示亦同。另外，中國大陸開始加強產品流通管理與上市後安全監視。為了因應新的法規並管理醫療器械，目前正提出 5 項草案，規定對醫療器械註冊草案 、規定對體外診斷器械註冊管理辦法草案、規定對醫療器械生產監督管理草案、規定對醫療器械的分銷商證照管理草案、規定的使用說明書和醫療器械的標記草案等。

2. **IMDRF：由 Notify Body BSI 的 Gert Bos, Head of Regulatory Affairs BSI Global 報告，IMDRF 最新的近況，摘述如下：**

（1）美國主導下各方面的影響：IMDRF 由各國輪流主導會議，2014 年由美國主導，跟過去一樣維持每年二次的 plenary meetings，但是有些工作小組可能會藉由增加 google

teleconference 來使進度往前，也包括個工作小組間的 teleconference，可能是每星期、每月或每季，依各工作小組進度而選擇合適的步調進行。

（2）IMDRF 近期成功評估進度：

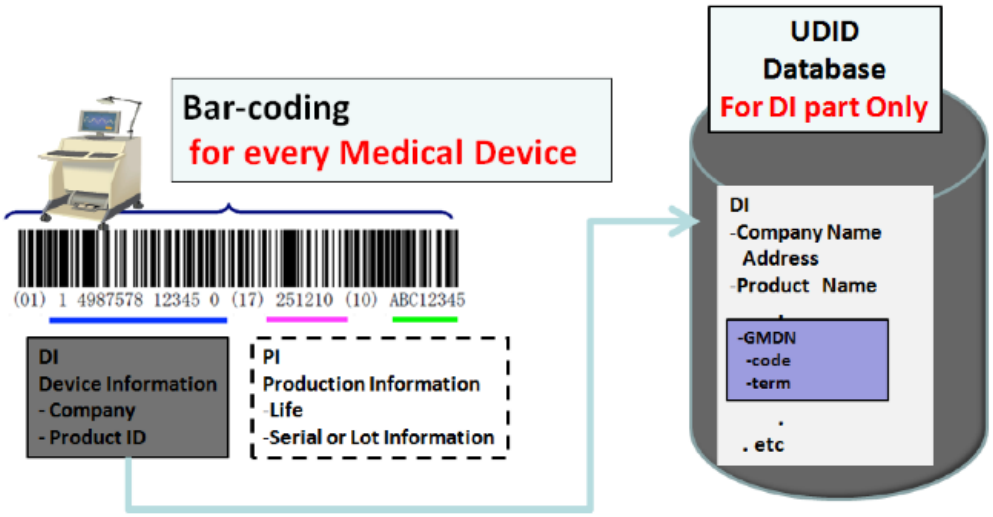
I. 獨立醫療器材管理軟體（Standalone Medical Device Software, SaMD software）的標準與法規調和：未來醫療器材軟體驗（如影像系統的軟體等）、硬體（器材類等）之審查與管理將會漸漸分開。基於醫療器材是以風險程度作為分類管理基礎，所以也將醫材軟體在上市前審查評估的資料也依據其所宣稱的用途（medical purpose）、臨床使用（context of use）、核心功能（core functionality）分成 Type I (very high impact), Type II (high impact), Type III (medium impact), Type IV (low impact)等，要求其所需要簡送的審查資料，未來希望每一類型之審查資料之階層也能獨立被管理（如下表）。

Summary of Controls	Type I	Type II	Type III	Type IV
Risk Management – ISO 14971	X	X	X	X
Software development lifecycle – IEC 62304 class A requirements			X	X
Software development lifecycle – IEC 62304 class B requirements		X		
Software development lifecycle – IEC 62304 class C requirements	X			
Labeling accompanying the device	X	X	X	X
Clinical effectiveness	X			
Clinical safety and performance	X	X		
Clear clinical efficacy statement accompanying the SaMD may be based on bench test, simulated, or already available set of data.			X	X

II. 重新評估 NCAR 安全資訊交換系統的運作：正研擬發展 2 種機制來強化安全資訊交換與傳遞分享。Stream 1 是嚴重不良反應，對於民眾健康有嚴重影響者（serious

public health issues），以雙向資訊溝通機制。另外 Stream 2 則是針對醫材回收警訊交換，則以單項傳遞機制進行。未來針對二種不同路徑溝通的安全資訊，不僅必須做定義以利清楚的知道哪一種安全資訊通報是要走 Stream 1 而哪一種是走 Stream 2，此外資訊通報表格也將一併修改於 N14（Guidance on new NCAR system）。

III. 由美國主導醫療器材辨識系統（UDI）落實的 roadmap：目前研擬的是針對所有風險等級的醫療器材，Bar-code 上所含資訊，包括製造廠與產品辨識資訊（Device information, DI: company and product ID）與產品相關資訊（product information, PI: life, sterile or Lot information etc.）。



這部份各國都才剛起步，必須再進行各國法規了解與差異分析之後才能進一步討論執行之路徑圖（roadmap）與法規調和。

IV. 獨立查核機構的評鑑機制（MD Single Audit Program）：部份已經是 final documents，包括 IMDRF MDSAP WG N3 – “Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition”, IMDRF MDSAP WG N4 – “Competency and Training Requirements for Auditing Organizations”, IMDRF MDSAP WG N5 – “Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations”, IMDRF MDSAP WG N6 - “Regulatory Authority Assessor Competency and Training Requirements”。另外還有一些正在討論預計今年會完成的，包括 IMDRF MDSAP WG N11 – consistent grading of non-conformities 將於 2014 年 9 月、N8 Reg. Auth. Assessment Method Guidance 將於 2015 年秋季完成。

V. 產品送件規定（regulated product submissions, RPS）：醫材產品上市前審查送件格式與文件，目前體外診斷試劑醫材（IVD）所採用的是 Common Submission Dossier Template (CSDT) format，而一般醫材（non-IVD）傾向用 Summary Technical Document (STED)為送件格式。

（3）IMDRF 對於亞洲區國家的法規調和目標：現階段 AHWP 是以正式觀察員代表參加，雖然泛太平洋區域中有日本、澳洲、中國是會員，IMDRF 也邀請亞洲獨立國家加入成為會員，然而現階段或未來並沒有具體的重點放在亞太地區。

3. **AHWP：Asian Harmonization Working Party** 由 Notify Body BSI 的 Dr. Gert Bos 報告，重點摘述如下：

（1）最近法規調和重點

I. WG1- Pre-Market Submission/CSDT 已完成產品上市前審查之資料送件格式 CSDT 到 STED 比對（Comparison between the GHTF Summary Technical Documentation (STED) formats for Medical Devices and In Vitro Diagnostic Medical Devices and the Common Submission Dossier Template (CSDT) format）。GHTF STED 送件格式對於醫材（MDD）之規定與 CSDT 送件格式對於體外診斷醫材（IVD）之要件。目前此部份正在進行對於 ASEAN 之法規差異分析與調和，另外上市前產品註冊軟體指南（Medical Software Guidelines for pre-market registration）正在傳閱預計於 2014 年 4 月完成意見蒐集，而複合式產品指南（Combination Products Guidelines）已於 2013 年底完成。

II. WG1a 已經於 2012 年完成 GHTF guidance on IVD, list of recognized standards for IVD, best practices for clinical evaluation and investigation on IVD，另外 Essential Principles (EP) of Safety and Performance of IVD Medical Devices、AHWP Regulatory Framework for IVD Medical Devices 與 Comparison between the GHTF Summary Technical Documentation (STED) formats for Medical Devices

and In Vitro Diagnostic Medical Devices and the Common Submission Dossier Template (CSDT) format 亦已於 2013 年完成。此外，正在進行的項目包括 AHWP guidance documents on IVD medical devices,舉辦相關 training activities 及研擬 affordable and accessible IVD (AAIVD) medical devices 之管理架構文件等。

III. WG2-PMS and Vigilance，產品上市後管理與監視：已完成醫材不良事件通報格式、上市後各項名詞定義、電子通報不良事件表格，新增針對醫材廠商或授權代理商之通報責任指引（Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative）。正在進行的工作項目包括安全警訊傳播系統（Safety Alert Dissemination System, SADS）升級、回顧 SADS 指引文件，對於藥商或授權代理商應通報不良事件與通報時限之要求。

IV. WG3 – Quality Management System (QMS)已完成並採用 N17, N18 文件，新增 Nonconformity Grading System for Regulatory Purposes and Information Exchange。目前正在進行的工作項目是針對進口商或經銷商申請產品上市前符合 ISO13485 之規定，此文件將擴及小規模製造廠（application of ISO13485 for importers/distributors），此份文件正在傳閱徵求意見。

V. WG4 – Quality System Audit 已經完成醫材製造廠品質文件系統之查核管理規定 1-5 部分，正在進行的部份是

針對進口商與經銷商（importers and distributors, I&D）申請查核的指引文件，同時規劃訓練模組。

VI. WG5 – Clinical Safety/Performance 已經完成 ICH GCP, SG5 GN, 新版 ISO14155 之比較，同時比較研究 AHWP 會員國之間對於臨床試驗管理與查核落實情形。目前正在進行臨床試驗查核之一致性、要求註冊申請的管理的概念、附加倫理委員之要求與訓練課程規劃文件等。

VII. WG6 – Capacity Building and Regulatory Training 已完成訓練課程需求蒐集與會員國間協調培訓計畫。目前正在進行的工作項目是，根據各工作小組提供的訓練需求，協助規劃訓練模組，並了解 WHO, APEC, RAPS 等國際組織之教育訓練重點，尋求協調合作培訓之可能。

VIII. STG – Medical Device Nomenclature 已完成國際醫材命名系統（Global Medical Device Nomenclature ，GMDN）推廣，持續參與 GMDN 機構, IMDRF 與 WHO 的醫材命名工作，提供建議予歐盟 DG SANGO 和 GMDN 機構，並於中國完成 5 個探討使用 GMDN 命名之可行性分析討論課程。目前正積極探討未來於 UDI 之應用，並指導 AHWP 會員國應用 UDI 之法規調和。

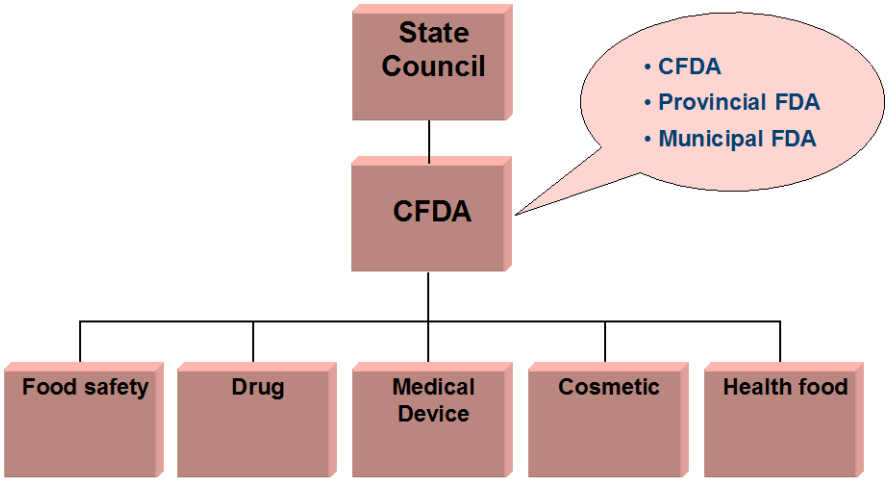
IX. 未來策略與方向：擴展 AHWP 之會員國，並訓練會員國建立能量，在 GHTF principles 與 AHWP guidance 基礎下調和管理法規，並積極與國際組織協調合作，如 IMDRF, APEC, ASEAN, WHO 等。

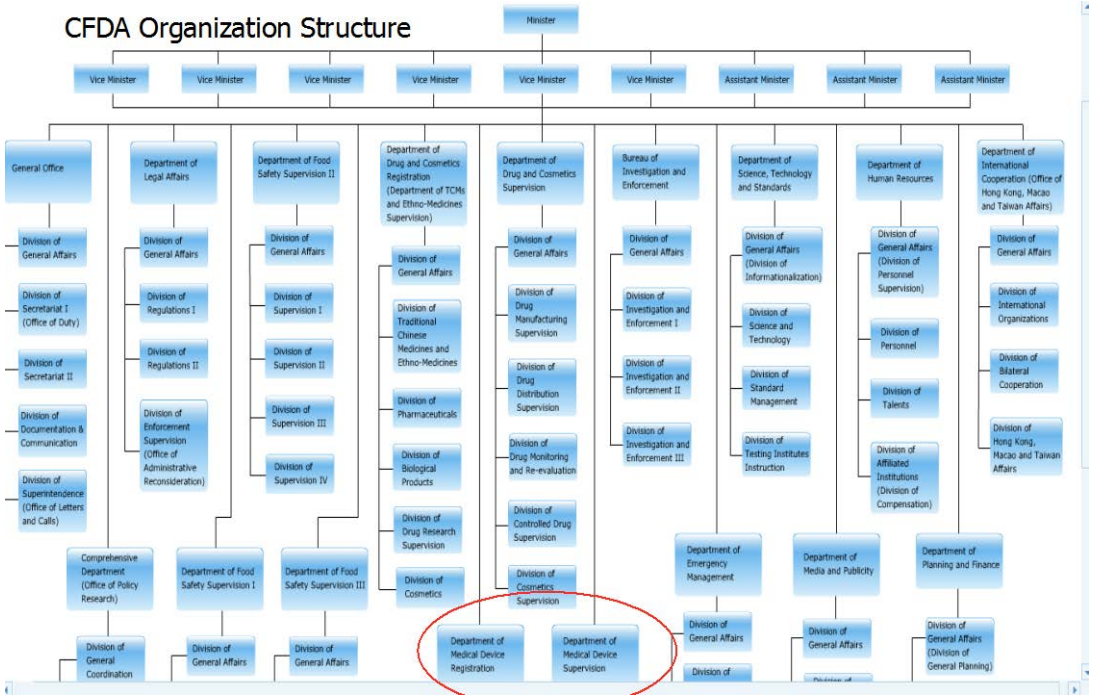
（2）法規調和下藥商與主管機關之效益：藉由教育訓練與資源分享，協助會員國建構醫材產品之法規管理能量，有利於各國法規逐漸調和，未來更有利於醫療器材產品在 ASEAN 區域上市。

4. 各國管理現況：中國大陸

（1）根據中國大陸第 12 屆全國人民代表大會第一次會議批准的「國務院機構改革和職能轉變方案」和「國務院關於機構設置的通知」，將原國家食品藥品監督管理局（State FDA, SFDA）進行改組，設立國家食品藥品監督管理總局（正部級；China FDA 以下簡稱 CFDA），為國務院直屬機構。隨之醫療器材的管理權責也有一些改變，簡化產品註冊與再次註冊之管理規定，強化產品流通管理與安全監管。管理醫材之單位有二的部門，Department of Medical Device Registration 與 Department of Medical Device Supervision。

CFDA
Website: http://eng.sfda.gov.cn/WS03/CL0755/





（2）目前因應新法規正擬訂的草案規定包括：醫療器械註冊辦法（Provision on Medical Device Registration）、體外診斷器械註冊管理辦法（Provision on IVD Device Registration）、醫療器械生產監督管理辦法（Provision on Medical Device Manufacturing Supervision & Administration）、醫療器械的分銷商證照管理辦法（Provision on Medical Device Distributor Licensure Administration）、醫療器械使用說明書和標示管理辦法（Provision on Instruction for Use and Labeling of Medical Devices）。

（3）醫療器械之註冊

I. 國產醫療器械：Class I 醫療器械產品只需自我宣告並將註冊登記表送到 Municipal FDA 備查即可以上市，Class II 醫療器械產品需向 Provincial FDA 申請註冊，並經 Provincial FDA 審核通過後即可以上市（無需上報

CFDA），而高風險之 Class III 醫療器械產品則需直接向 CFDA 申請註冊，經審核通過後才准予上市。

II. 輸入之醫療器械：全部都必須送交技術性文件至 CFDA 註冊，第一等級醫材經核備後才能上市，而第 II 或 III 等級醫材則需經審核後許可才能上市。

III. 技術文件的需求：只要是需要註冊或審查的案件，都必須提送下列文件資料：Product risk analysis, Product technical requirements, Product testing report, Clinical evaluation data, Draft IFU and Label, QMS documentation related to product design and production, Other documents to demonstrate safety and effectiveness of products。

IV. 註冊發證與證延續：這一部分是新的，過去中國人民共和國醫療器械註冊証效期是 4 年，當證的效期屆滿後，藥商需再重新提出資料註冊取得新的註冊証。新法之後，醫療器械註冊証效期延長為 5 年，且可以延續，所以 re-registration 改成 renewal，此對於醫療器械製造廠是件好消息。

V. 產品流通運送需符合流通規範，且需經註冊登記核准，只要由省級 FDA 批准即可，Distribution Enterprise License 效期為 5 年。Class I MD 不需要，Class II MD 只需繳交註冊登記表備查，Class III MD 則需要註冊經審核通過後許可，而且必須符合產品可追溯的系統（traceability requirements and IT system）。此外，製造廠如果也是經銷商，則必須符合運銷規定與驗證的紀

錄。

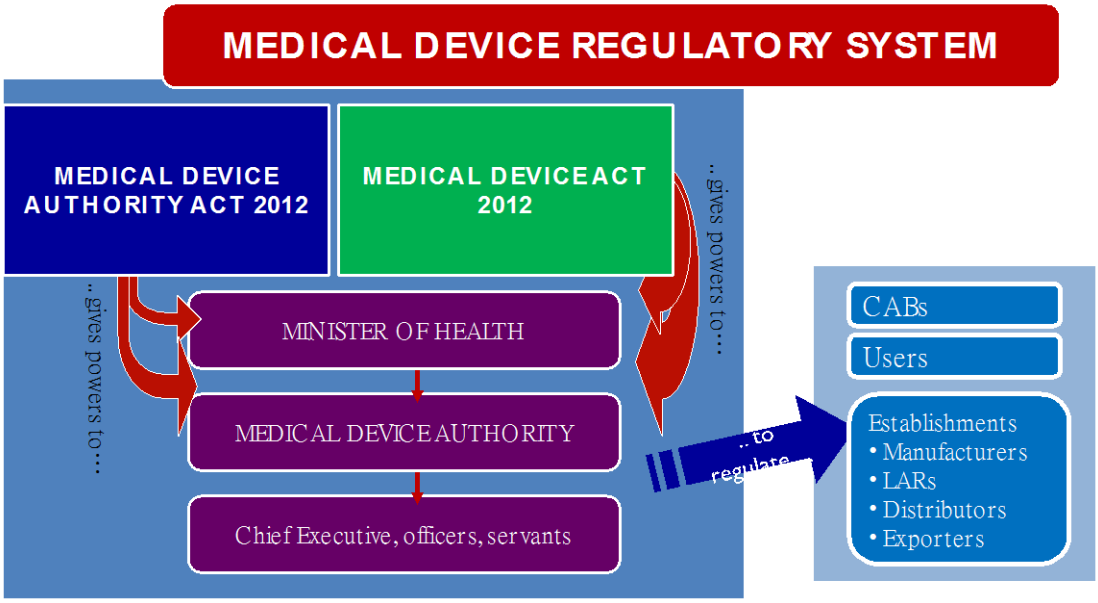
（二）第二天會議（6 月 4 日）：韓國、ASEAN、臺灣、馬來西亞之情形，各國體外診斷醫療器材之管理現況

1. 馬來西亞：馬來西亞的醫療器材相關法規主要是依據WHO recommendations, GHTF recommendations, WTO agreements, ASEAN's Medical Device Directive, AHWP recommendations等國際建議規範，產品也是以風險等級分類，主要是參考GHTF之風險等級分成四級，由低-A到高-D風險，low risk (Simple surgical instruments, tongue depressor, thermometer, examination light, simple wound dressing, oxygen mask, stethoscopes), low-moderate (Hypodermic needles, suction equipment, anesthetic breathing circuits, aspirator, external bone growth simulators, hearing aids, hydrogel dressings, patient controlled pain relief, phototherapy unit, x-ray films), high-moderate (Lung ventilator, orthopedic implants, baby incubator, blood oxygenator, blood bag, contact lens disinfecting/cleaning products, deep wound dressing, defibrillator, radiological therapy equipment, ventilator), high risk (Pacemakers and their leads, implantable defibrillators, implantable infusion pumps, heart valves, inter-uterine contraceptive devices, neurological catheters, vascular

STAGE	**PRE-MARKET**	**PLACEMENT ON-MARKET**	**POST-MARKET**
Regulated persons	• Manufacturer/ authorized representative • Importer	• Manufacturer/ authorized representative • Distributor	• Manufacturer/ authorized representative • Distributor • User
Regulated items/ activities	• Product safety & performance • Manufacturing • Labeling	• Supply chain • Advertising	• Surveillance & vigilance • Usage, maintenance, disposal
Regulatory activities	• Pre-market review • Inspection & audit	• Registration • Advertisement control	• Monitoring • Inspection & audit • Enforcement

prostheses, stents)。從原型設計到上市後相對應的法規如下表，

馬來西亞衛生主管機關深知，如果政策不能以法規來規範是無法真正落實，於是醫療器材產品相關的規範於 2012 年國會通過 Medical Device Act 與 Medical Device Authority Act，因此成立 Medical Device Authority (MDA)，其權責包括落實實施醫療器材法規，並對執行法律提出建議與改革、鼓勵促進產業發展、建立諮詢輔導服務（收費制度），同時也提供獎勵或貸款服務。

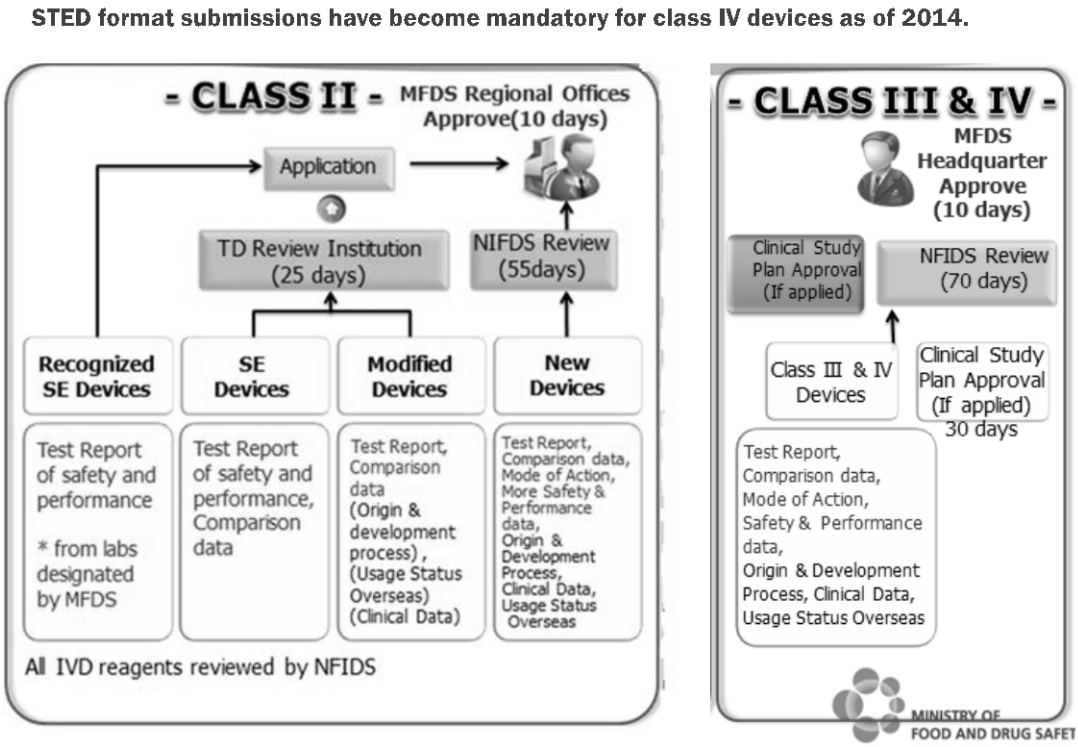


2. 臺灣：針對我國醫療器材全生命週期的風險管理概念、法規與實際執行經驗與過去成果、創新產品與我國研發產品的成功例子、的國際合作現況與未來重點與將推行的重點政策（包括醫療器材單一辨識系統 UDI，醫療器材優良流通規範等）報告，報告內容如附件 2。
3. 韓國：雖然韓國的醫療器材產品輸入產值比出口產值高，然而自 2010 年以來，出口之醫療器材產值以 13.7%年成長率逼近進口產值的年成長率 4.7%，以 2013 年為例，進口產值約 2.88 billion (USD)，而出口產值以成長至 2,47 billion (USD)。2009 年韓國衛生

部核准的醫療器材許可品項約 2429，然而至 2013 年核准醫療器材已 2 倍成長達 5817 品項。在輸出品項中以超音波影像診斷儀器居冠，其次是軟性隱形眼鏡，第三出口醫材是牙科植入物。輸入產品則以軟式隱形眼鏡居冠，其次是管狀動脈支架，第三位則是 MRI 影像系統。在這樣的市場趨勢下，甫於 2013 改組的食品藥物安全監部(Ministry of Food and Drug Safety, MFDS，前 the Korea Food and Drug Administration, KFDA）在 2014 年公布第四等級（即相對於美國的第三等級)高風險醫療器材必須以 STED 送件格式申請醫療器材上市前審查（此與我國現行規定是一致的）。MFDS 中醫療器材職掌單位 Medical Device Safety Bureau 下有三個 Divisions 分別權管醫療器材政策擬定（Medical Device Policy Division）、醫療器材管理（Medical Device Management Division）、醫療器材品質管理（Medical Device Quality Division），另外還有一個 MD Evaluation Department 審查第三與第四等級醫療器材之技術性文件，同時授權第三機構（the Third-Party Organization）協助審查第二等級之醫療器材。由中央主管機關授權第三機構審查 Class II medical device 的作法與日本授權 Recognized Certification Bodies 審查很類似。在韓國 Third-Party Organization 協助審查是 Medical Device Act 授權成立，支持並提供臨床試驗查核、安全監視參考或標準、教育訓練等訊息予 MFDS，這些 Third-Party organization 包括醫材試驗實驗室、醫材製造品質查核機構、技術性文件審查機構、醫材臨床試驗中心以及醫材產業公協會。韓國醫材產品的分級予審查單位審查內容簡述如下表：

Device Classification	Regulatory Path	Review Party	Number of Classified Devices
Class I	Minimal Risk	Forceps for medical use	601
Class II	Low Risk	Syringe, Infusion Pump	1008
Class III	High Risk	Coronary stent, PTA Balloon Catheter (Class II => IV)	254
Class IV	Moderate Risk	Silk Suture, Contact lens	341

不同風險等級之醫材送件與審查時間如下圖：



4. ASEAN：東南亞國協(The Association of Southeast Asia Nations, ASEAN）目前 7 個會員國，包括新加坡、馬來西亞、印尼、泰國、越南、緬甸、菲律賓等，另外 Brunei, Cambodia, Laos 等國雖非正式 ASEAN 會員國，但是醫療器材產品的管理規定正依據 ASEAN 相關規定發展制定中。ASEAN 成立的目的是為了促進東南亞國家經濟成長與競爭，去除區域貿易投資障礙，同時調和區域產業之法規。醫療器材產品相關管理法規之調和，主要是由 ASEAN Consultative Committee on Standard and Quality （ACCSQ）項下的 Medical Device Product Working Group （MDPWG）依據 ASEAN Medical Device Directive （AMDD）來執行（1）醫療器材產品於 ASEAN 上市之一般審查程序與送件格式（ASEAN Common Submission Dossier Template, ACSDT）、調和會員國之間文件審查送件格式的差異、上市後醫療器材警訊通報格式，（2）制定 AMDD 的 road map，於法的層級上統一定義醫療器材，分類

分級，各分級產品之審查與核准原則，產品標示與 CSDT 內容（3）落實標準與指引文件，（4）臨床試驗查核等。第 18 屆 ASEAN ACCSQ-MDPWG Meeting 於 2014 年 5 月 6-9 日舉行，由馬來西亞醫療器材管理處長 Zamane Bin Abdul RAHMAN 主持，新加坡 HAS 的 Johanna KOH 協同主持，決議重點包括：（1）AMDD 由高級經濟官員代表會議（Senior Economic Officials Meetings, SEOM）核准，將於 12 月 31 日以前完成會員國簽署，隨即馬來西亞針對第 17 條提出有關貿易問題的討論，此有可能影響 AMDD 簽署期程，（2）成立亞洲醫療器材委員會（Asia Medical Device Committee, AMDC）監督 AMDD 於此區域落實情形。同時由印尼主導主管機關與產業界之教育訓練需求。

5. 體外診斷醫療器材：目前體外診斷醫療器材在亞洲區域各國家（包括：Australia, China, Hong Kong, India, Japan, Malaysia, Singapore, South Korea, Taiwan）的管理規定岐異性大，急需調和。

（1）澳洲：自 1989 年，將 IVD 的管理規定，訂於 Therapeutic Goods Act 中第 4 章 Medical Devices 直到 2010 年 7 月 1 日將 GHTF 所建議的 IVD 相關規定一併納入新修訂的 Therapeutic Goods Act（Amendment of Therapeutic Goods Regulation, ARTG）中。自 2014 年 7 月開始，所有的治療用的 IVDs 和 class IV in-house IVDs 都必須經過註冊核准程序才能在澳洲上市。因此澳洲於修訂之 ARTG 中重新定義體外診斷醫療器材，並將檢測遺傳基因預測疾病發生之檢測試劑也囊括在內。與一般醫療器材分級一樣，從低風險到高風險，將 IVDs 分成 class I (no public health risk or low personal risk), class II (low public health risk or moderate personal risk), class III (moderate public health risk or high personal risk), class IV (high public

health risk)，這些相關法訂於 ARTG 之 3.1 Medical Devices, Regulations 2002 中，對於 IVD 的註冊與審查規定則規範於 3.2 & 3.3。註冊與審查程序與加拿大和歐盟之程序相近。命名是採 Global Medical Device Nomenclature (GMDN) code，Class I 是採自我宣告（declaration conformity to Australia requirements），Class II and III IVD 則是需自我宣告符合法規，且其製造廠符合法規證書是必須的，海外製造廠提供的證明書在澳洲是可以接受，而高公共衛生風險的 class IV 不論是當地或是海外製造廠，都必須經過 TGA conformity assessment。

（2）中國大陸：在新的 No. 650 命令中，公布醫療器械與 IVDs 的新註冊管理規定，並於 2014 年 6 月 1 日生效。在中國大陸，IVDs 跟一般醫療器械的管理是一樣的，依風險等級（low to high）分成 class I, class II, class III，但是用於血液來源篩選與放射性標的的試劑則是以藥品來管理。IVDs 在註冊時必須要一併檢送製造品質系統資料、註冊審查上市需求資料、產品流通管理和上市後監視管控資料文件，而 IVDs reagents 則必須遵照 2007 年 6 月公布的 section 3 management method of IVD reagents registration，註冊-No. 229 和 No. 230、審查需求文件文件-No. 609、臨床試驗-No.240。Class I 主要是微生物培養液作為檢體培養之用途，class II 包括蛋白質、血糖、荷爾蒙、酵素、維生素、無機離子、藥物和它的代謝中間產物檢測、自體免疫抗體、微生物鑑定或藥物過敏分析測試、其他生化免疫功能相關檢測等，class III 包括致病原（抗原）抗體檢測試劑、血型檢測、遺傳疾病之基因型檢測、血中藥物或毒性濃度檢測、腫瘤標記檢測和過敏反應相關檢測等。比較特別

是，中國大陸的 IVDs 包含 IVD instrument + IVD reagents，上市前需要二種產品的註冊許可。

（3）香港：現階段並無 IVDs 相關的管理法規，而醫療器械則由成立於 2004 年的 The Medical Devices Office（MDCO）逐步依據 GHTF 的建議落實醫療器械的管理，2009 年 12 月 1 日先公布列管 class D IVD 醫療器械，隨後 Guidance note (GN)-6 公布列管 IVD 以及申請模式。其 IVDs 之風險分級是參考 GHTF 的分級建議，分成 class A, B, C 和 class D，相關的分類分級與定義規定於 Technical Reference TR-006: Principle of In Vitro Diagnostic Medical Devices Classification。

（4）印度：現階段並無專法規範體外診斷醫療器材，有些甚至是以藥品來管理，規定於 Central Drugs Standards Control Organization（CDSCO）中，管理的 IVDs 指引，公布於公報中並張貼於 CDSCO 網頁中。現階段只列管用於檢測 HIV、HBsAg、 HCV、血型測試和癌疾測試試劑，註冊認證和輸入許可是必要的，而且於 2013 年 1 月 1 日生效的 Guidance Document，將醫療器材的認證採註冊與再註冊方式管理，也就是許可證屆期時需檢送所有的文件資料再次申請註冊審查，經許可後才能繼續於印度販售。另外 2013 年 11 月 15 日公布生效的 Guidance Documentation for Import License of Notified and Non-notifies Diagnostic kits 是規定列管和未列管的檢測試劑輸入許可送件格式。目前尚有些制訂中的醫療器材法規，包括 Medical Devices Regulation Bill 2006、2009 年 CDSCO 公布的 Draft Schedule M-III 對於醫療器材定義規定、風險四等級的分級規定、2013 年 Drugs and Cosmetics (amendment) Act 等。在 Drugs and Cosmetics (amendment)

Act 中也對醫療器材定義：A device which is reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system whether used alone or in combination thereof intended to be used for examination and providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body or animals。

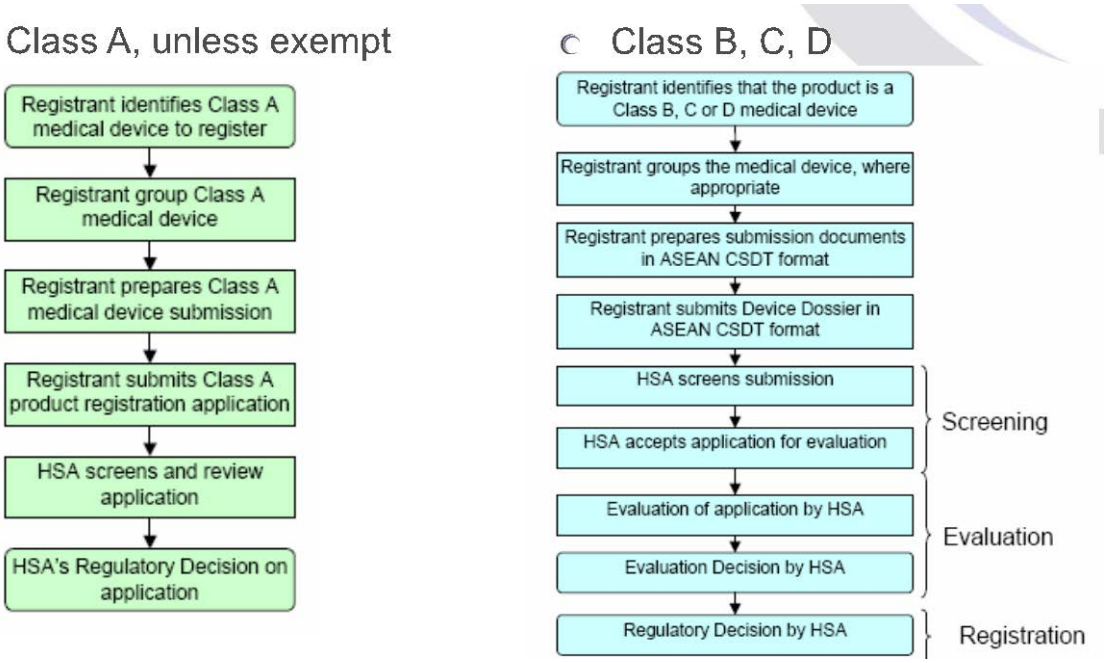
（5）日本：Pharmaceutical Affairs Law (PAL), amended 2013 有很大的變革，對於Good manufacturing practice授權the 3rd party 查核與發證，取代過去必須由厚生勞動省（MHLW）認證的管理，且規定許可證持有者（market authorization holder, MAH）的管理系統。此外日本採認國際標準，包括國際命名系統GMDN（譯成Japan MDN）、醫療器材風險四分級、參考ISO13485 的GMP認證和summary Technical Documentation, STED送件格式。PAL amendment於去年 11 月 20 日通過公布，醫療器材管理法規獨立專章，對於第三認證機構可以查核認證的範圍進一步擴大至更多的class II（目前約有 75% class II JMDN code是由第三認證機構認可）、class II、class IV（參考下表，日本醫療器材分級認證機構與審查時間），未來醫療器材的軟硬體管理將會獨立，取代現在軟硬體合一的管理系統，而且PMDA將更早介入醫療器材產業的輔導

Third-party certification and product approval system

Device Classification	Regulatory Path	Review Party	Requirement
Class I: General Medical Devices	Notification/self-certification	PMDA (0 months)	Product notification (non-approval process)
Class II: Controlled Medical Devices	Nin-sho Certification: products compliant with certification standards	Recognized certification body (3-6 Months)	The recognized certification body assesses conformity to the certification standards and QMS. The certification standards comprise the nomenclature and JIS as technical standards.
Class III: Specially Controlled Medical Devices	Shonin Approval from MHLW	PMDA (8-16 months)	Submit application documents to prove the device's safety and effectiveness have been demonstrated per Article 40, Paragraph 1 of PAL, Enforcement Regulations
Class IV: Specially Controlled Medical Devices			

（6）馬來西亞：醫療器材於馬來西亞是由衛生部下之醫療器材管理處（The Medical Device Bureau, MDB）管理，自 2006 年開始，鼓勵自願申請註冊登記，逐步推動醫療器材註冊審查制度，直到 2012 年 12 月 31 日於公報中刊登 The Medical Device Act 2012 (Act 737)，生效於 2013 年 7 月 1 日，緩衝期 2 年（http://www.mdb.gov.my/mdb/），分別有四個草案指引 Draft guidance on essential principles of safety and performance of IVD medical devices, Draft guidance documents on IVD medical device classification system, Draft guidance document on principles of conformity assessment for IVD medical devices, Draft guidance documents on common submission dossier template of IVD medical device。

（7）新加坡：醫療器材和 IVD 主管機關是 Health Science Authority（HSA），遵循 2007 年制定公布的 Health Products Act，海外醫療器材製造廠，其產品需由領有優良醫療器材流通基準證明（Good Distribution Practice for Medical Devices, GDPMDS）的公司輸入。今（2014）年 5 月進一步公布的 GN-14 Guidance on Risk Classification of In Vitro Diagnostic Medical Devices，GN-15 Guidance on Medical Device Product Registration，GN-18 Guidance on Preparation of Product Registration Submission for In Vitro Diagnostic Medical Devices 使用 ASEAN CSDT 送件格式。審查流程如下圖，class A to D，風險由低到高。



審查路徑主要有二種，精簡審查（Abridged evaluation），主要是對於那些醫療器材，已在 US FDA, EU notified body, Health Canada, Australia TGA, Japan MHLW 等 5 個國家的主管機關審查通過的產品，送件時品質文件資料（包括包裝、標示、說明書、臨床用途）必須與前述 5 個主管機關所審查的資料一樣。另一種則是一般審查路徑，除了前述精簡路徑審查的產品外，需有全套的文件審查。

（8）韓國：於 2013 年新修訂醫療器材法（Medical Device Act，MDA），而且從 2013 年 1 月開始，IVDs 的管理與一般醫療器材一樣，主管機關是 Ministry of Food and Drug Safety（MFDS，即前 KFDA），因此 IVDs 的分級也是比照一般療器材分成四等級，class I 是不需要技術審查也不需要 KGMP 而且是透過網站上登錄通知，而 class II 依據先前 MFDS 已經核准過的醫療器材的相似度（substantial equivalency, SE）分成四種，分別是(i) Announced Equivalent (i.e. no technical document review required to get product approval); (ii)

Equivalent (iii) Improved (iv) Novel 等，其中 equivalent, improved and novel 的醫療器材必須通過全套資料的技術文件審查。Class III 和 class IV 產品也是必須送全套技術性文件審查，而那些 non-SE, high risk 產品必須執行臨床試驗。除了 class I 醫療器材外，其他醫療器材產品要在韓國上市，必須先取得 KGMP 認可，此與 ISO 13485 或 US 21CFR part 820 相似、販售證明與產品許可證明。最近韓國為了加速 MDA 法規與國際調和，擴大落實 GHTF 建議指引，朝向擴大接受國際標準，和施行國際醫療器材審查法規。於 2014 年 1 月 28 日公布新修正的 MDA 並將於 2014 年 7 月 29 日生效。

（三）第三天會議（6 月 5 日）：日本、印度、澳洲、紐西蘭情形，各國仿單標示管理現況：

1. 中國大陸：從 2004 年 7 月開始，醫療器械要在中國大陸市場販售必須有標籤和說明，2012 年通知國外產品輸入中國大陸必須有中文包裝、標籤和說明書，並自 2013 年 4 月生效。法規規定標示包括下列的標示方法與內容（1）產品名稱、型號、規格；（2）法定製造廠名稱和廠址；（3）實質製造廠名和廠址；（4）製造廠於中國大陸之代理商名稱及其詳細聯絡資訊；（5）許可證字號和醫療器械名稱；（6）許可證字號和技術基準；（6）產品的臨床效能及其應用；（7）禁忌、注意事項和警語等；（8）符號、數字、圖形、縮寫和標記說明；（9）插圖、操作方式和安裝圖形表達；（10）儲存環境、條件與方法；（11）滅菌方法和架儲期；（12）通過的技術檢驗或測試標準之內容。以上，如有一項未依法規標示完整，則無法被核准上市。
2. 日本：依據日本藥事法 PAL 2005 規定，海外製造廠之醫療器材於

日本必須有法定代理商（marketing authorization holders, MAH）將產品送件，經審查許可（Ninsho certification）後輸入，標示（instruction for use, IFU）必須包括（1）醫療器材產品名稱、型號、規格；（2）說明書核准日期與最近更新版本與日期；（3）許可證號碼，Ninsho ID number；（4）產品的分類分級；（5）臨床效能與說明；（6）禁忌、注意事項與警語；（7）操作說明或指引；（8）儲存期限與保存方法；（9）產品的批號；（10）滅菌方法與維持儲存指引等，此外 MAH 名稱與地址也必須詳細刊載，標示或說明書必須是日文版本。

3. 印度：醫療器材的標籤或標示可以接受英文版本，所採用的是參考國際標示標準 EN 980 和 ISO 15223-1 and -2，一般標示和包裝則依據 Legal Metrology Act 2009，內容則與日本規定相近，但另外要求必須標示消費者服務專線與銷售最高價格。
4. 澳洲：TGA “Therapeutic Goods Regulations 2002 schedule 1 part 2, Australia regulatory guidelines for medical devices （ARGMD）規定醫療器材產品的標示必須是英文版本，內容與日本的規定大同小異。
5. 韓國：醫療器材的產品標示規定於 Medical Device Act No. 10564，於 2011 年 4 月 7 日公布，同年 10 月 8 日生效，其中 Article 20 規範標示與容器包裝等應遵循事項。標示或說明書都必須是韓文。
6. 東南亞國協 ASEAN：雖然 ASEAN 有對於醫療器材標示相關規定，但是個會員國仍然有自己國家的規定，且文字均以各會員國自己的國家語文為主。新加坡於 GN-23 Guidance on labeling for medical devices，製造廠址和代理輸入商之聯絡電話是選擇性標示並未強硬規定。馬來西亞 Malaysia Medical Device Regulation 2012 規定，於馬來西亞申請註冊販售的醫療器材必須附當地語言 Bahasa

Malaysian language，尤其是由一般消費者非專業人員使用的產品，法定代理商名稱和地址是必要標示。此外，特別值得注意的是，在泰國不僅要標示法定製造廠（legal manufacturer），實際受委託之製造廠（physical manufacturer）與國別都要標示，如 Product is manufactured packaged and labeled at company X in Germany for Company Y in Switzerland。

7. 產品識別各國現況：雖然東南亞區域各國家對於產品的標示均有規定，包括產品的批號、型號等，但是為了產品的辨識，各國仍積極推動 UDI。中國大陸正規劃 UDI 相關法案，將於 2014 年底公布；日本目前強制規定 class III 和 class IV 需具備 UDI 識別系統與資料上傳；韓國目前只對於植入性超過 1 年以上，或是生命支持性之醫療器材規定必須具備 UDI 識別系統；澳洲則規劃於未來與紐西蘭醫藥衛生整合（ANZTPA）時再規劃醫療器材執行 UDI 之方向；印度則尚未要求。

8. 澳洲與紐西蘭：二個衛生主管機關基於堅強的科學背景將整合成一個國家實驗室的概念，將醫藥產品的管理規定、審查基準、分類分級和上市後管理規定等朝向資源共享與區域整合模式，希望未來 Australia and New Zealand Therapeutic Products Agency（ANZTPA）在一套法規下，可以加速產品於紐澳之間的流通與上市後安全資訊共享與監控機制下，確保產品的品質、效能和安全。基於歐盟、GHTF、英國對於醫療器材之管理法規類似，因此目前澳洲接受歐盟認證（CE, European certificate）上市之產品精簡審查進入澳洲市場。但是對於嵌入性（integral）和含有生物性成分（如 animal components, recombinant or human origin components）之第三等級醫療器材則除外，必須經由 TGA 審查不能走快速審查程序。TGA 未來與紐西蘭的整合進度，由第三認證機構符合性評估

與第三等級醫療器材製造廠之更嚴格查核機制優先於 2015 年 7 月以前完成，接著完成 Hips, knees and IVDs 之相關法，搭配醫療保險制度，最後完成 ANZTPA 改組架構。目前在 ANZTPA 籌備階段，僅有 B2B projects 資訊分享、上市後不良事件安全通報與回收通報網路與資訊 之整合與共享機制，另有 14 個相關法規調和中（包括 prescription and non-prescription medicines, medicines ingredients, safety, medical devices, biological and blood products 相關法規）。

參、心得及建議

一、心得：

1. 綜整前述各國對於醫療器材從上市前到上市後的全生命週期管理法規，我國相對其他亞洲區國家，不論在上市前審查或是上市後安全監控機制，法規調和不僅未落後於紐、澳、ASEAN 個會員國、日、韓各國，甚至走在亞洲區其他國家前面。但是在法規的落實面其實有很大的進步空間。或許是因為文化差異，我國廠商在法規的遵從面如能確實落實，其實產品要走出台灣市場放眼亞洲或中國大陸並不困難。各與會國家代表對於我國產業輔導機制，開放友善的討論空間均予以高度的肯定，且表示法規環境的建構有吸引外資來臺投資的意願。但由於我國市場值不大，即使有友善的投資環境，也不會是外商投資首選的市場。

2. 我國對於體外診斷醫療器材之管理，自 2003 年開始將 IVDs 全面當成醫療器材管理，相關法規亦然。此比其他亞洲區域其他國家更早將 IVDs 全面參照一般醫療器材的風險等級分類與管理模式；如新加坡自 2007 年才開始訂有 IVDs 之法規，且於 2014 年 5 月才更新法規，將 IVDs 參照醫療器材之風險等級與管理模式；馬來西亞則於 2013 年才在政府公報中公布 2 年後 IVDs 比照醫材之風險管理模式；韓國於 2013 年由 KFDA 改組成 MFDS 之後，才將 IVDs 全面以一般醫材管理模式列管，但對於第 1 等及之醫材只要在網路上宣告登錄即可，毋須註冊亦無要求 GMP；澳洲在 2014 年 7 月最新修訂的 ARTG 才將 IVDs 全面比照醫材管理模式；中國大陸也是在 2014 年 6 月才將 IVDs 全面依據醫材的風險分類分級與管理模式列管；而香港與印度等國家甚至尚無 IVDs 法規。基於此優勢，我國能在亞洲醫療器材法規調和會議（AHWP）中主導 Working Group 1a (WG1a)調和體外診斷醫療器材上市前審查相關法規，實

有助於我國醫療器材產業之外銷，邁向國際市場。只要我國製造產業，好好落實符合醫療器材相關法規管理模式，我們有信心能成為國際大廠的委託製造對象，臺灣製造醫療器材進軍國際市場，提升出口產值是可以實現的目標。

3. 醫療器材單一辨識系統 UDI 於各國也都是正在起步的階段，我國先機於 102 年開始分析研究國際法規，今（103）年開始籌備研擬建置我國 UDI 系統並規劃實施期程，預計 104 年開始輔導產業執行 UDI 系統，此與亞洲區大部分國家同步規劃前進；中國大陸正規化 UDI 相關法案，將於 2014 年底公布，日本目前強制規定 class III 和 class IV 需具備 UDI 識別系統與資料上傳，韓國目前只對於植入性或是生命支持性之醫療器材強制規定必須具備 UDI 識別系統，澳洲則規劃於未來與紐西蘭醫藥衛生整合成 ANZTPA 後，在規劃醫療器材執行 UDI 之方向。故而我們更確信我國對於醫療器材管理法規的國際化，也為我國醫療器材產業開啟與國際接軌的橋樑。

4. 我國專案諮詢輔導產業獲得國際上各國醫療器材廠之肯定，包括 OLYMPUS, Jonson & Jonson, TUV, BRNDWOOD-BIOMEDICAL 等大醫療器材商及機構，私底下向職表示他們曾有醫材送審時遇到法規問題，但都獲得 TFDA 友善的回應與討論。顯示 TFDA 醫材管理法規與國際接軌，不僅協助我國醫藥產品走向國際市場，也為輸入國內的醫材產品開啟輔導溝通之門，並成功的吸引外商引入醫藥產品至我國。

5. 醫療器材流通管理：我國已於去（102）年底公布醫療器材優良流通規範草案，目前仍在輔導業者主動試行查核階段。目前除了新加坡有規定輸入新加坡的產品必須檢具符合 GDP 的證書，而中國大陸在最近修訂的醫療器械法規中也同樣要求要在中國大陸上市的

產品必須符合 ISO 13485 優良製造規範外，同時要檢附符合 GDP 證書才可以。日本則要求製造廠應負起產品流通之品質與安全，因此在查廠時會一併查核。我國現行階段，雖然國產廠實地查核時也會看產品輸送程序，但是對於代理商或委託販售則沒有規範，因此在後市場檢查計畫中，如發現不符合規格的產品常常找不出原因，因此積極輔導廠商，溝通後，宜儘速要求製造廠和藥商都必須符合 GDP 才能確保產品的流通安全。

二、建議

1. 醫療器材仿單與標示合法性：藥事法第 75 條雖已規定標籤、仿單或包裝應依法標示，我國對於醫療器材產品的仿單或標示，有幾項值得思考精進的建議：

（1） 法定製造廠名與廠址和受託實際製造廠名廠址均需完整標示。因為目前委託製造的產品很多，大多數實際製造廠（ physical manufacturer ）與法定製造廠（ legal manufacturer）可能不同國家。雖然依據藥事法，所有產品責任，由法定製造廠負全責，然而法定製造廠對於實際製造廠之製造情形，常常也只有仰賴一紙證書，無法確切的了解實際製造過程情形，導致產品於市場上，如經查驗不合格時，難以調查釐清問題所在。此部分，中國大陸和泰國都要求必須同時標示法定和實際製造廠的廠名廠址。此種作法的好處，是對消費者資訊透明，確保消費者選購產品之選擇。

（2） 仿單載明最新更新日期與版本：我國現行醫療器材仿單並未強制規定註記仿單最新更新日期與版本，且有部分更新是可以自行更新留廠備查，因此廠商如能將最新更新版本之日期加註，不僅表示仿單標示的動態式符合法規要求，也表示製造廠對於產品上市後，仍然持續維持優良製造規範，更確保

消費者購買產品時可以取得最新的產品資訊。尤其是有些注意事項、不良反應或警語等。此作法，於日本以法規要求標示，中國大陸也研擬跟進，韓國於 2011 年修訂醫療器材相關法規時也將仿單標準版本作法制規定。

（3） 仿單註記產品核准時之規格與採用標準與版本：目前醫療器材產品於核准上市時，並未強制要求將送審之產品材質、規格及所採用之標準完整標示於仿單中，如能要求仿單中註記詳細產品材質、規格與採用標準此有助於食藥署於後市場監控時，經檢驗疑似不符合規格時，常需進一步釐清所驗市售品之材質、規格與檢驗方法或所採用標準，因此如能於及時更新的仿單中詳細記載這些資訊，則可以增進上市後主動產品品質監控與調查之效率。此於日本、韓國都已要求仿單需註記產品之材質、規格與檢驗標準，中國大陸新修訂的醫療器材相關法規中也已納入此項。**只是，如果我國亦要朝此方向規劃，預期變更案件會大量增加，必須同時考慮人力的增加才有量能辦理驟增之變更案件**。

（4） 綜上，建議可以依法研擬醫療器材仿單中文標準版本供廠商製作仿單時遵循。此部分，TFDA 醫粧組前已經規劃簡要版公布於本署網站（http://www.fda.gov.tw/tc/siteContent.aspx?sid=2266#.U8-cm4CSy8w）供藥商參考，詳細版本亦已在規劃中。

2. 第一等級醫療器材上網登錄制度：現階段似乎只有我國對第一等級醫療器材的管理最為嚴格，大部分國家（美國、日本、英國、中國大陸、澳洲、韓國等）都是採自主式管理，廠商自己上網登陸宣告符合 GMP 然後就可販售，主管機關既不審查也不發許可證，但是

主管機關保留 for cause inspection 或審查權力。也就是說上市後如果在市場上發現有不合格產品，隨時可以要求廠商繳交技術性資料供審查或機動性去查廠。尤其韓國，甚至直接就規定第一等級醫療器材不需要符合韓國的優良製造規範（KGMP）我國雖然大部分第一等級醫療器材自我切結後可以採臨櫃註冊，廠商並不需要檢送技術性文件，我們也不審查，然後立刻發出許可證。可是對於上市後的產品又難控管其品質。亦即，相信廠商的切結，卻又經常發現廠商所切結內容並不正確，增加很多醫粧組上市後監控的負荷。醫粧組目前正修訂中的醫療器材專章（法），亦參考國際上一般管理規定，以後可以採上網登錄自主管理制度，希望可以獲得上級機關和行政立法院的支持，不僅能與國際接軌，也能聚集我國醫療器材審查能量，提升審查效能。

3. 區域性臨床試驗合作：國際上對於醫療器材的管理幾乎都是採風險等級方式管理，對於高風險、植入式或無類似品之醫療器材均要求需於國內執行臨床試驗。目的除了臨床效能之外也要確保醫材使用於臨床上並不會有人種差異的風險。為了加速病人可以取得有效的醫療器材，簡省臨床試驗計畫執行期間，聯合無人種差異之亞洲區域國家，聯合執行臨床試驗，彼此承認臨床試驗計畫報告，應該是可以努力的國合方向。

4. 聯合查廠之可行性：比較各國家對於醫療器材製造廠的管理規定後，發現幾乎大家都是採用 ISO 13485，即使是美國採用 quality system regulation 較為嚴格，也是涵蓋了 ISO 13485，因此產品於國際上流通時，不論到哪一個國家都要被查一次，或是檢送品質文件系統供審核，主要是各國家對於別國家的查廠能力不盡然信任。如果彼此之間對於查廠品質還不信任，無法接受各國的查廠報告，或許可以先就從 joint inspection 開始，這樣實質國際合作的好處是

可以節省廠商為了官方來查廠而耗費周章準備，例如日本如要來台灣海外查廠時，食藥署也可以安排同一時間去查那一家醫療器材廠，藉此彼此了解查廠重點與彼此稽查員的品質。不僅提升信任度，更可以朝向未來彼此承認查廠報告的目標努力。

5. 量能極需提升：韓國自從改組成 MFDS 之後，管理醫療器材業務的部門不僅獨立擴編組織，尤其海外查廠的人力與訓練。為強化醫材的管理與監督，將 monitoring, evaluation 的責任轉移至 regional food and drug administration，同時擴大與 Third-party organization 的合作，包括 13 個醫材試驗實驗室、4 個 GMP 查核機構協助 MFDS 查核與認證第二等級醫療器材、6 個 technical document review agency 等，都是在擴增專業審查人力與機構，因應日益擴增的醫療器材產業需求。中國大陸去年修法之後，CFDA 轄下更有 provincial FDA, Municipal FDA 分層負責不同風險等級的醫療器材，人數更是倍增，預計 2017 年以前可以開始進行海外查廠。日本 MLHW 與 PMDA，也在去年新修正的藥事法中將不同風險等級的醫療器材授權予 PMDA 之外，甚至給第三認證機構來審查與發證，不僅如此，PMDA 的人數也從原來的 400 多人增加到今年已有 700 多人。欲善其事必先利其器，有足夠的量能才能全方位的監管，落實醫療產品的生命週期管理。

附件一、Agenda of "Informa LifeScience Medical Device and IVD Regulations in Asia Pacific Area" at London

Day 1: Tuesday , 3 June

08:30 Registration opens

09:00 **Opening remarks from the Chairperson**

China

09:10 **Examining registration requirements and the latest expectations from the Chinese FDA (CFDA) for imported medical devices**

- Understanding the regulatory approval system for medical devices in China
- Outlining the expectations for local representation of foreign manufacturers
- Highlighting proposed changes to medical device regulation and the timetable for implementation
- Discussing license renewals and the need for re-registration of products
- Understanding local testing requirements for Chinese regulatory assessment: Where, when and by whom?
- Preparing for customs and import requirements of pre-approved and post approved devices
- Outlining the fundamental changes to clinical trial requirements for medical device assessments in China

Lane Ji, Scheme Manager & Specialist, **BSI,** China

09:45 **Case study: Successfully gaining regulatory approval for a high risk medical device in China**

CASE STUDY • Outlining the internal and external factors for successful approval

- Differences between International Standards, Chinese National Standards and Product Registration Standards
- Discussing experiences of local product testing: Expectations, challenges and lessons for peers
- Understanding the submission requirements including software summary reports

Ed Woo, AP RA Director, **Varian Medical Systems Pacific Inc.,** Hong Kong

10:20 Morning coffee and networking

10:55 **Case study: Navigating the regulatory pathway for a low/medium risk medical device in China**

CASE STUDY • Outlining the tasks and responsibilities of local representatives, affiliates or distributors in the registration process

- Illustrating how the regulatory pathway was navigated, the challenges encountered and how these could have been avoided
- Discussing experiences from central CFDA offices, CMDE reviewing process, and expectations
- Examining how the dossier was compiled for regulatory approval and how potentially

confidential information was communicated

• Sharing experiences of local product testing and essential lessons learned

• Assessing how new and unexpected requirements were managed and complied with

Sarah Hempel, Regulatory Affairs Manager, **Olympus Winter & Ibe GmbH,** Germany

Navigating regulatory pathways in China

11:30 **Experience Exchange: Worked examples of navigating the registration pathway in China**

EXPERIENCE EXCHANGE Join a case study leader as they guide their round-table through the regulatory pathway for their medical device. Openly discuss each step of the regulatory approval, share your experiences and learn from others.

China (high risk device) **Arkan Zwick,** Director, Regulatory Affairs and Legal, **CROMA Pharmaceutical,** Austria

Alexandra Baer, Regulatory Affairs Manager, Asia Pacific and LATAM,**CROMA Pharmaceutical,** Austria

China (low risk device) **Joan Drejer,** Director Regulatory Affairs, **Coloplast AS,** Denmark

Experience exchanges are highly interactive sessions where attendees can share their questions and knowledge. Attendees will be split into small groups to enable them to share solutions to common problems with other delegates in a less formal environment.

Regulatory harmonisation

12:20 **FLASH UPDATE from the Asian Harmonization Working Party (AHWP)**

FLASH UPDATE • Examining recent progress and achievements of the AHWP

• Outlining current and future harmonisation projects from the working party

• Highlighting benefits realised for manufactures and competent authorities

Gert Bos, Head of Regulatory & Clinical Affairs, Healthcare Department, **BSI,** UK

12:45 Lunch and networking

13:45 **FLASH UPDATE from the International Medical Device Regulators Forum (IMDRF)**

FLASH UPDATE • Examining the impact of US FDA assuming the chair of IMDRF in 2014

• Assessing recent work and success of the IMDRF

• Discussing IMDRF objectives in Asia Pacific

• Highlighting current and future harmonisation projects from the IMDRF

Gert Bos, Head of Regulatory & Clinical Affairs, Healthcare Department, **BSI,** UK

Post market surveillance, adverse events and recalls

14:10 **Reviewing country-specific requirements and sharing considerations for post market surveillance Asia Pacific**

• Outlining where post market surveillance requirements exist in Asia Pacific

• Examining country-specific post market surveillance requirements and expectations: What are the obligations of the manufacturer and local representative?

• Discussing developing post market surveillance requirements in Asia Pacific, what can be expected and when?

Céline Malo, International Regulatory Affairs Consultant, **meditec Consulting GmbH,** Switzerland

14:45 **Complying with adverse event reporting and recall procedures across Asia Pacific**

• Reviewing adverse event and recall procedures in countries of the Asia Pacific region

• Examining adverse event reporting: What, when, how and to whom to report?

• Highlighting developing or emerging requirements for adverse event reporting and recall procedures

• Assessing requirements for reporting adverse events from outside of the country or region

• Practical considerations for incorporating reporting into international reporting strategies

• Providing case study examples of adverse event reporting and product recalls in Asia Pacific

Marta Carnielli, Safety Risk Management & Surveillance Manager, **Ortho Clinical Diagnostics (a Johnson & Johnson Company),** France

15:20 Afternoon tea and networking

Developing regulatory strategies

15:55 **Case study: Developing efficient regulatory strategies for multiple market approval across the Asia Pacific region**

CASE STUDY • Examining how countries were grouped and an order of approach established to create an efficient approval pathway across Asia Pacific

• Illustrating how the reuse of documents and information across dossiers and submissions can be achieved

• Outlining approval timelines and experienced delays

• Exploiting clinical trial data for maximum applicability and approval in multiple countries

• Leveraging market approvals in EU/US and capitalising on mutual recognition arrangements in Asia Pacific

• Success, failures and what would have been done differently

Susana De Azevedo Waesch, Head of Global Regulatory Affairs, **Geistlich Pharma AG,** Switzerland

Medical device software regulation

16:30 **Discussing current and emerging regulations governing standalone and integrated software and medical devices**

• Identifying current guidance for the regulation of medical device software in Asia Pacific

• Addressing developing and emerging regulation for standalone and integrated medical device software

• Examining regulatory expectations on validation and testing of medical device software

• Balancing the extent of information required by Competent Authorities with confidentiality concerns

Tim Lin, Senior Technical Consultant, Greater China, Medical Regulatory Advisory Services, Health Science, **UL,** Taiwan

17:05 **Closing remarks from the chairperson**

17:10 End of conference day one

17:30 Registration for evening seminar X: **Communicating and negotiating with Competent Authorities**

EXPERIENCE EXCHANGE

Day 2: Wednesday, 4 June

08:30 Registration opens

09:00 Opening remarks from the Chairperson

Updates from regional Competent Authorities

09.10 Sharing practical experience and the latest updates for medical device regulation **in Malaysia**

- Assessing what industry can expect from new medical device regulation in Malaysia
- Asking how the new medical device regulation in Malaysia compares to the AMDD
- Analysing what information and data will be required for registration in Malaysia
- Outlining the timelines for transition and implementation of new regulation in Malaysia
- Sharing practical experience of gaining market approval in Malaysia to date

Zamane bin Abdul Rahman, Chief Executive, Medical Device Authority, Ministry of Health Malaysia, Malaysia

Taiwan

09:45 FLASH UPDATE and insight on market approval requirements and expectations in Taiwan

FLASH UPDATE • Examining medical device classification in Taiwan

- Overcoming difficulties in definitions and implications of legal manufacturer and country of origin status
- Outlining language and submission requirements for market approval in Taiwan
- Essential considerations for reference products and already markets comparable products

Yu-wen Ruby Huang, Section Chief, Division of Medical Devices and Cosmetics, Taiwan FDA (TFDA), Taiwan

10:10 Morning coffee and networking

Korea

10:45 Evaluating recent regulatory change in Korea and the implications for industry

- Examining the Korean Medical Devices Acts of 2013 – how have regulations changed?
- Addressing new Korean GMP expectations and inspections
- Highlighting new requirements for the use of Summary Technical Documentation (STED) in applications to Korea
- Discussing the use of 3rd party assessments and reviews by the Korean Ministry of Food and Drug Safety (MFDS)
- Outlining recent changes to the regulation of medical device software in Korea
- Analysing recent changes to IVD regulation in Korea

Tony Yip, Manager of Quality Assurance and Regulatory Affairs, Far East Region, Elekta Limited, Hong Kong

11.20 Case study: Sharing practical advice and key lessons learned from pre-market approval in Korea

CASE STUDY • Discussing the tasks and responsibilities of local affiliates and representatives in the registration process

- Examining how the regulatory pathway was navigated, challenges encountered and how this could have been avoided
- Overcoming challenges presented by the 2013 Korean Medical Devices Act
- Assessing what level of detail was required and submitted to the authorities in supporting dossiers
- Practical considerations for incorporating Korea into regulatory strategies for Asia Pacific

Eric Verstegen, Regional Manager, Regulatory Affairs, Convatec Thailand Co., Ltd., Thailand

ASEAN

11.55 Providing an essential update on the ASEAN Medical Device Directive, its implementation and implications for industry

- Examining the ASEAN Medical Device Directives (AMDD): What is proposed and how does this compare to the EU MDD?
- Addressing customs and import requirements contained within the AMDD
- Outlining timelines for completion, approval and implementation of the AMDD
- Discussing the consequences of implementation and potential for harmonisation in ASEAN
- Assessing the use of international regulatory standards under the AMDD
- Essential advice for integrating ASEAN countries into existing regulatory strategies

Philippe Auclair, Senior Director, Regulatory Strategy & Advocacy, Abbott Quality & Regulatory EMEA, Abbott Laboratories, Inc, Belgium

12:30 Lunch and networking

13:30 Evaluating regulatory requirements and expectations for market approval in Singapore

- Comparing and contrasting new Singaporean medical device laws with the AMDD
- Providing a breakdown of the documentation requirements for medical device market approval in Singapore
- Assessing post-approval changes to medical devices in Singapore
- Analysing the assessment and review strategy in Singapore, how does this compare to neighbouring countries?
- Sharing practical experiences of medical device marketing applications to Singapore

Bernd Henningsen, Regulatory Affairs Manager, Hocoma AG, Switzerland

14:05 Evaluating regulatory developments in Indonesia, Philippines, Thailand, Vietnam and other ASEAN countries

- Defining current regulatory requirements and expectations for medical devices

- Outlining the need for local representatives and their responsibilities
- Addressing the remaining barriers to entry and their importance for regulatory teams
- Examining the latest progress towards adoption of the AMDD and timelines for implementation
- Highlighting remaining differences between countries after implementation of the AMDD
- Discussing regulatory progress in Brunei, Cambodia, Laos and Myanmar (Burma)

May Ng, Regulatory Affairs Director, Biosensors International, Singapore

14:40 Afternoon tea and networking

15:15 Understanding the use and requirements of the Summary Technical Document (STED) and Common Submission Dossier Template (CSDT) formats

- Understanding STED and CSTD formats, their similarities, differences and use
- Providing a status on adoption and use of STED and CSTD by Asia Pacific countries
- Making a comparison between the submission and the technical file
- Demonstrating what is required for STED and CSTD and how they should be populated
- Discussing where additional information to the STED and CSTD may be required

Karen Nicholls, Director International RA, Olympus Surgical Technologies America, UK

K: IVD Registration

15:50 Examining IVD specific requirements and expectations across Asia Pacific

- Reviewing how IVDs are classified across countries of the Asia Pacific region
- Successfully meeting IVD-specific regulation where it differs from medical device regulation
- Discussing proposed IVD software regulation changes in Korea and Japan
- Evaluating IVD-specific labelling requirements across Asia Pacific

Céline Malo, International Regulatory Affairs Consultant, meditec Consulting GmbH, Switzerland

16:25 Case study: Sharing lessons learned from gaining market approval for IVDs in countries of the Asia Pacific region

CASE STUDY • Highlighting country specific difficulties encountered when navigating the regulatory pathway for IVD registration

- Outlining the requirements and use of local representatives in regulatory strategies across Asia Pacific
- Examining how dossiers were compiled and information/data shared between submissions
- Developing labelling strategies to ensure compliance across multiple markets
- Key considerations for managing new and unexpected regulatory requirements for IVD registrations
- Sharing feedback and advice from interaction and communication with regulatory agencies

Oyinkan Donaldson, Global Regulatory Affairs Manager, LifeScan (a Johnson & Johnson company), UK

17:00 Closing remarks from the Chairperson

17:05 End of conference day two

17:30 Registration for evening seminar Y: Understanding registration requirements for medical devices in Russia and key CIS countries

Day 3: Thursday, 5 June

08:30 Registration opens

08:50 Opening remarks from the Chairperson

Japan

09:00 Examining the change from Pharmaceutical Affairs Law (PAL) to “The Law for ensuring quality, effectiveness and safety of pharmaceuticals and medical devices etc.” in Japan

- Timelines for the revised new law and expected enforcement in November 2014
- Outlining the regulatory requirements for medical devices
- Examining requirements for pre-marketing approvals and certification of medical devices
- Discussing changes for quality management system inspections
- Assessing requirements for risk management in addition to applying ISO 14971
- Highlighting the use of 3rd party assessment bodies in Japan

Yasushi Murayama, Manager, INFOSERVICE Group, TÜV SÜD Japan Ltd. & former Vice Chair (2004-2005), Association of Registered Certification Bodies under PAL (ARCB), Japan

09:35 Case study: Practical advice for the successful registration of medical devices in Japan

CASE STUDY • Establishing local representation in Japan: What is required and what are the challenges to be overcome?

- Examining what level of detail is required when compiling dossiers for market approval in Japan
- Highlighting registration challenges encountered, how these were overcome and lessons for future applications
- Comparing Japanese regulatory requirements with those of Korea and China, and formulating the most efficient APAC regulatory strategies
- Developing a company-wide strategy (with QA, Engineering, and Purchasing) to build the company system that supports meeting the PMDA raw material requirements
- Sharing experiences of interaction with the Japanese Competent Authority: What was gained and what could have been done differently?

Kyungyoon Kang, Regulatory Affairs Team Lead, Cook Incorporated, USA

10:10 Morning coffee and networking

India

10:45 Reviewing current registration requirements, recent changes and proposed changes under the Drugs and Cosmetics (Amendment) Bill in India

- Understanding the current classification and registration process for medical devices in India
- Addressing regulatory changes introduced in 2013 for medical devices
- Outlining submission file requirements and information requested by the competent authorities
- Providing clarification on country or origin, legal manufacturer, manufacturing location and the implication for labelling
- Examining the latest changes to clinical trial requirements in India, including: Application requirements, ethics committee approval and informed consent procedures
- Examining what is proposed under the Drugs and Cosmetics (Amendment) Bill and when this can be expected

Philippe Auclair, Senior Director, Regulatory Strategy & Advocacy, Abbott Quality & Regulatory EMEA, Abbott Laboratories, Inc, Belgium

11:20 Case study: Practical considerations for successful product registration in India

CASE STUDY • Interpretation Indian medical device law and required registration processes

- Outlining the registration pathway and lead-times in India
- Examining documentation requirements and corresponding application formats
- Highlighting technical presentation requirements
- Working with the DCGI: General considerations and communication strategy

Emma Louise Winch, International Regulatory Affairs Manager, Biomet International, UK

Labelling

11:55 Reviewing labelling requirements for medical devices across Asia Pacific

- Comparing and contrasting labelling requirements across the Asia Pacific region
- Illustrating how label and PIL requirements differ

- Key considerations for maximising label suitability for multiple markets whilst ensuring compliance to individual regulations
- Overcoming challenges involving date and manufacturing details on device labels
- Outlining local language, neighbouring language and English language acceptability across Asia Pacific
- Outlining commitments and progress towards the Unique Device Identifier (UDI) in Asia Pacific

Georges Hakim, Regulatory Affairs Manager, Medela AG, Switzerland

12:30 Lunch and networking

Asia Pacific World Café: China, Japan, Korea, ASEAN, India

INTERACTIVE SESSION

13:30 Asia Pacific World Café

WORLD CAFÉ Join the café chairperson and other attendees as they share experiences about the country, its particulars and the challenges faced. Get your questions answered before joining another café table concerning another country before the time is up! Café chairpersons will share novel findings from the discussion with the whole audience.

China: Ed Woo, AP RA Director, Varian Medical Systems Pacific Inc., Hong Kong

Japan: Sarah Hempel, Regulatory Affairs Manager, Olympus Winter & Ibe GmbH, Germany

Korea: Tony Yip, Manager of Quality Assurance and Regulatory Affairs, Far East Region, Elekta Limited, Hong Kong

ASEAN: May Ng, Regulatory Affairs Director, Biosensors International, Singapore

India: Eric Verstegen, Regional Manager, Regulatory Affairs, Convatec Thailand Co., Ltd., Thailand

14:30 Afternoon tea

Australia & New Zealand

15:00 Current expectations and future possibilities for a merged regulatory agency of Australia and New Zealand: What's right for regulation of smaller markets?

- Outlining the Australian registration system: Direct TGA conformity assessment, CE acceptance and self declaration
- Defining the existing pre market assessment requirements for medical devices in New Zealand

- Addressing the proposal for a single joint regulatory agency (ANZTPA) and the surrounding debate concerning a new premarket model
- Discussing what is ‘right’ for these comparatively small markets reliant on imported devices which have often already been assessed elsewhere

Arthur Brandwood, CEO and Principal Consultant, Brandwood Biomedical, Australia

Post Approval Change Management

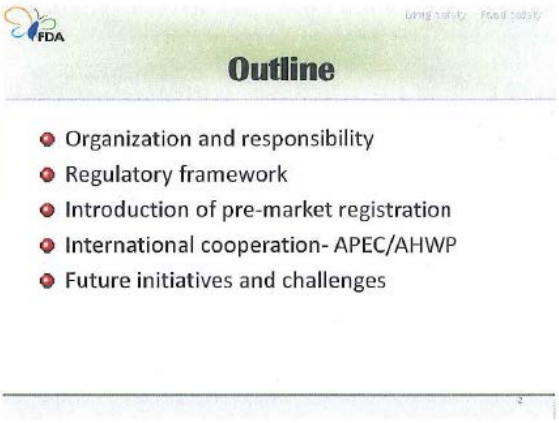
15:35 Analysing post market approval change requirements across Asia Pacific

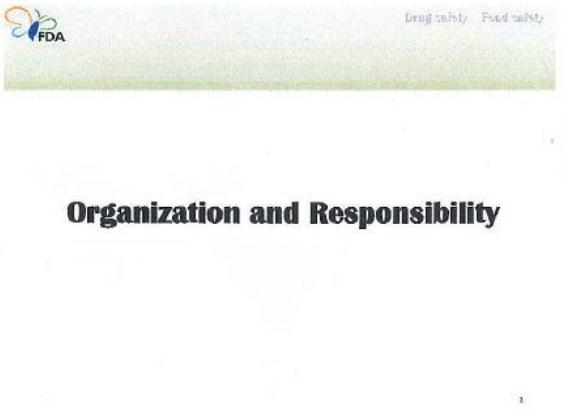
- Evaluating where post market change requirements exist for medical devices
- Establishing changes to your medical device as minor or major
- Assessing what changes require updating or re-registration of medical device devices
- Sharing practical experiences of registering post approval change in Asia Pacific

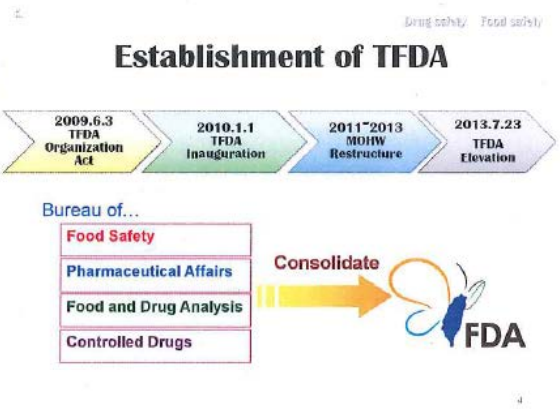
Karen Nicholls, Director International RA, Olympus Surgical Technologies America, UK

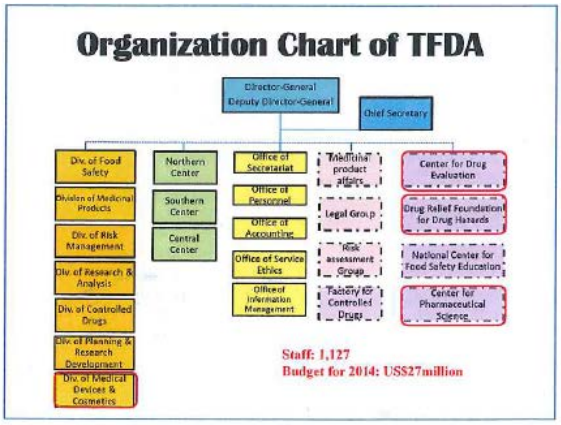
16:10 Closing remarks from the Chairperson

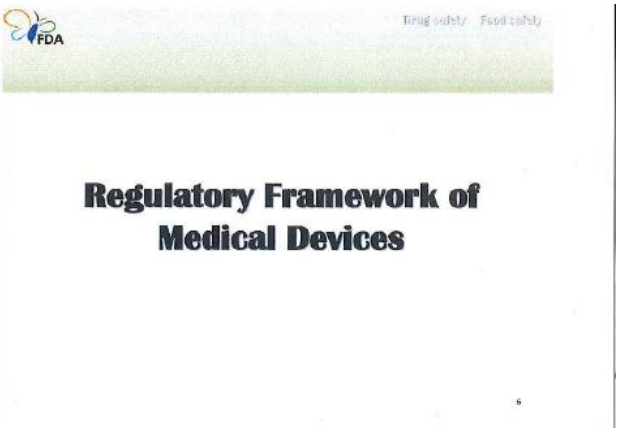
附件二、Flash Update and Insight on Market Approval Requirements and Expectations in Taiwan

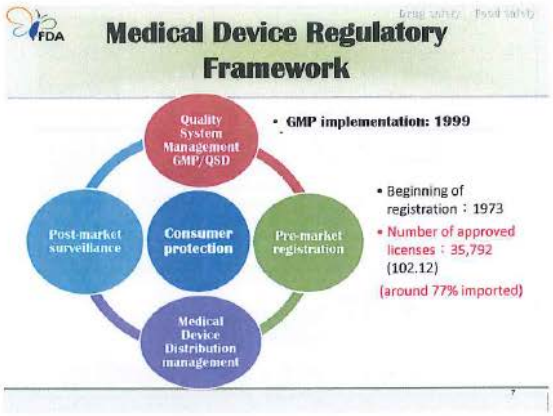


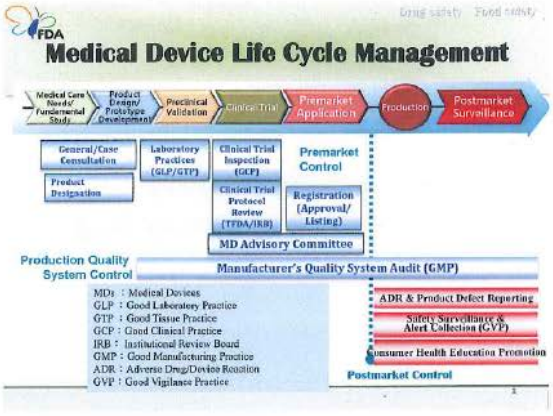


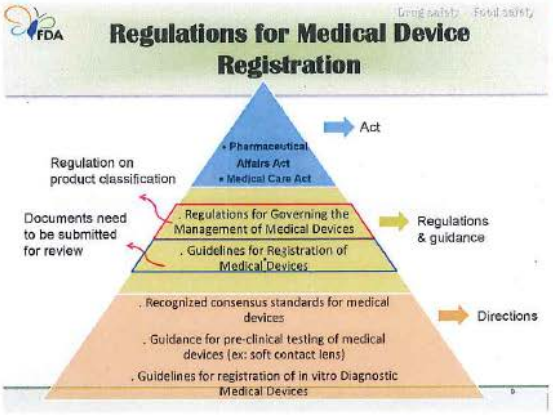




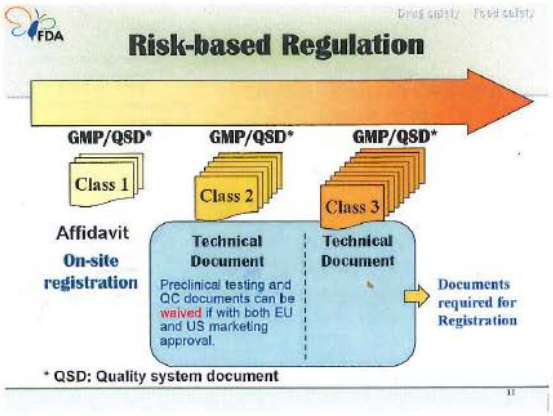


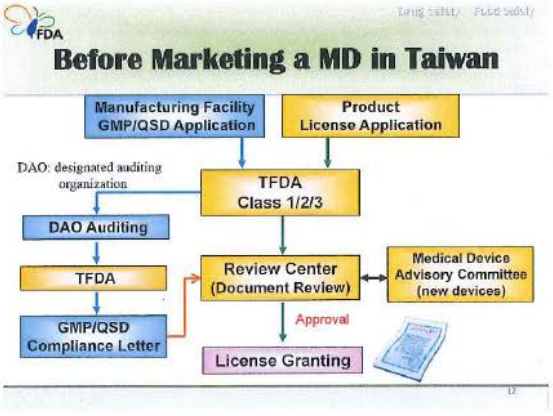

Medical Device Regulatory Framework
Quality System Management GMP/QSD
Post-market surveillance
Consumer protection
Pre-market registration
Medical Device Distribution management
• GMP implementation: 1999
• Beginning of registration：1973
• Number of approved licenses：35,792 (102.12)
(around 77% imported)


Medical Device Life Cycle Management
Premarket Control
Production Quality System Control
Manufacturer's Quality System Audit (GMP)
MD Advisory Committee
Postmarket Control
MDs : Medical Devices
GLP : Good Laboratory Practice
GTP : Good Tissue Practice
GCP : Good Clinical Practice
IRB : Institutional Review Board
GMP : Good Manufacturing Practice
ADR : Adverse Drug/Device Reaction
GVP : Good Vigilance Practice

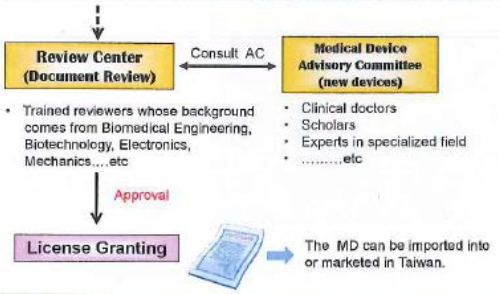

Regulations for Medical Device Registration
Act
• Pharmaceutical Affairs Act
• Medical Care Act
Regulation on product classification
Documents need to be submitted for review
. Regulations for Governing the Management of Medical Devices
. Guidelines for Registration of Medical Devices
Regulations & guidance
. Recognized consensus standards for medical devices
. Guidance for pre-clinical testing of medical devices (ex: soft contact lens)
. Guidelines for registration of in vitro Diagnostic Medical Devices
Directions


Introduction of Pre-market Registration


Risk-based Regulation
GMP/QSD*
GMP/QSD*
GMP/QSD*
Class 1
Class 2
Class 3
Affidavit
On-site registration
Technical Document
Preclinical testing and QC documents can be waived if with both EU and US marketing approval.
Technical Document
Documents required for Registration
* QSD: Quality system document


Before Marketing a MD in Taiwan
Manufacturing Facility GMP/QSD Application
Product License Application
DAO: designated auditing organization
TFDA Class 1/2/3
DAO Auditing
TFDA
GMP/QSD Compliance Letter
Review Center (Document Review)
Medical Device Advisory Committee (new devices)
Approval
License Granting

Composition of Review Center and Advisory Committee (AC)



- Trained reviewers whose background comes from Biomedical Engineering, Biotechnology, Electronics, Mechanics....etc
- Clinical doctors
- Scholars
- Experts in specialized field
- .....etc

Change and Development for IVD Regulation

1987 2000 2003 2005 2014

(1) Since 1987, the Hepatitis , HIV, HTLV and Anti-A, Anti-B Blood grouping test were needed to apply for biologic license.

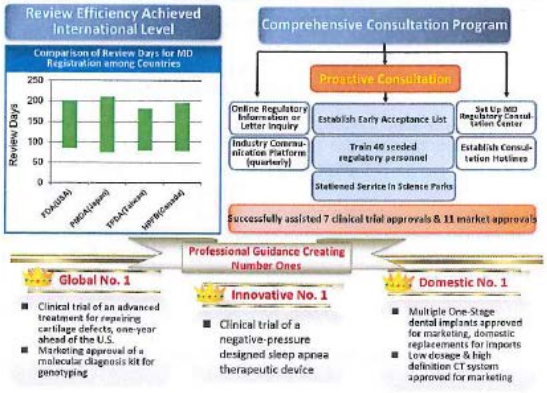
(2) On 21st June 2000, MOHW (former DOH) announced the medical device regulations. The new regulations request all medical devices be registered prior to sale. The transition period is 5 years.

(3) In 2003, MOHW announced the new framework, IVDs regulated as medical devices

(4) On June 21, 2005, all IVDs on market must be registered prior to sale.

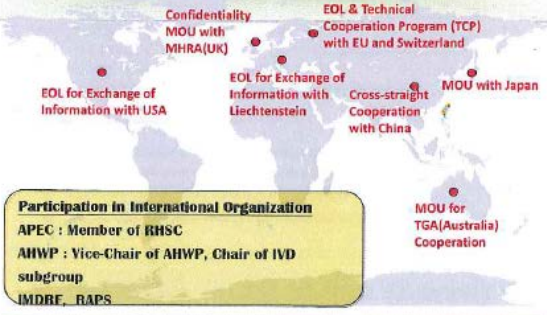
(5) Moving toward EP/STED submission format.

Achievements of MD Review and Consultation



International Cooperation

International Cooperation



APEC RHSC

- Goal
  - Improve public health and innovation by strengthening efficiency and effectiveness of regulatory authorities and reducing overall regulatory burden
- Membership
  - Regulators from 10 APEC Economies including Canada, China, Chinese Taipei, Japan, Korea, Mexico, Peru, Singapore, Thailand, US
  - Industry representatives
  - Director of APEC Harmonization Center

Priority Work Areas (PWAs)

- Roadmap developed by champion economy for each PWA
- Champions/PWAs identified to date
  - * Good Review Practices (Chinese Taipei)
  - Combination Products (Chinese Taipei)
  - MRCTs (Japan)
  - * Supply Chain Integrity (US)
  - Biotech Products and Pharmacovigilance (Korea)
  - GCP Inspection (Thailand)
  - * MRCT COE (Singapore)
  - Cellular Therapies (Singapore)

* Funding support from APEC

Good Review Practices (GRevP) Roadmap

- Goal
  - To strengthen the performance, predictability and transparency of regulatory agencies through the implementation or enhancement of Good Review Practices (GRevP) stepwise in each interested APEC economy by 2020
  - To enhance mutual trust for regulatory convergence among economies
- Specific Activities and Timeframe
  - Step 1 (2011-2012): Gap Analysis Survey for Setting the Foundation for Stepwise GRevP Implementation
  - Step 2 (2011-2014): Planned Solution to Address Gap
  - Step 3 (2012-2015): Assessing the Impact of GRevP Training and Exchange of Regulatory Information
  - Step 4 (2015-2020): Reaching the Goal for Achieving Common Regulatory Elements

Medical Device Combination Products Concept Note

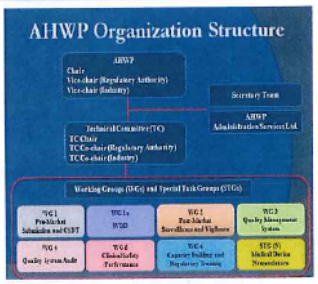
- Goal
  - To promote regulatory convergence among member economies for combination products regulated as medical devices throughout the product life cycle
- Activities Completed
  - Concept Note: endorsed Aug. 2012
  - Workshop: "2012 APEC-AHC-AHWP Joint Workshop on Medical Device Combination Products" held in Taipei Nov. 2012
  - Gap Analysis Survey among APEC member economies: Completed July 2013
- Future Activities
  - Round-table discussion among interested APEC economies

Introduction of AHWP

- Established in 1999
- To study and recommend ways to harmonize medical device regulation in the Asian regions (later expanded to other regions) and to work in coordination with other international organizations such as RAPS, APEC and IMDRF
- 23 member economies
  - Abu Dhabi, Brunei Darussalam, Cambodia, Chile, Chinese Taipei, Hong Kong SAR, China, India, Indonesia, Jordan, Kingdom of Saudi Arabia, Laos PDR, Malaysia, Myanmar, Pakistan, People's Republic of China, Philippines, Republic of Korea, Singapore, South Africa, State of Kuwait, Thailand, Vietnam, Yemen

Membership and Structure

- **Consist of industry and regulator representatives**
- **Chair**
  - **Dr. Saleh Al-Tayyar Saleh (SFDA)**
- **Vice-chair**
  - **Regulator: Li-Ling Liu (TFDA)**
  - **Industry: Lindsay Tao (Johnson & Johnson)**



AHWP Prioritized Work Area

- AHWP membership expansion
- Training & capacity building
- Harmonization in key areas based on GHTF principles
- Working alongside with APEC towards Regional Regulatory Harmonization goal by 2020
- Increase AHWP's global presence

TFDA Achievements in AHWP

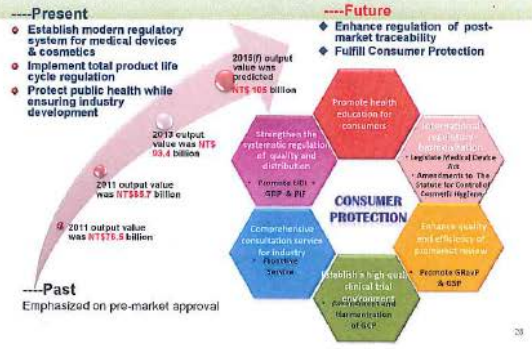
- Member since its establishment
- Representative in each workgroup
- Joined the post-market surveillance program Safety Alert Dissemination System (SADS)
- Lead Workgroup 1a – IVD
  - Four AHWP guidance on regulation of IVD are endorsed in AHWP Annual Meeting, 2013
  - Hold trainings for AHWP member economies on IVD regulations
  - Collaborate with LSHTM on Affordable and Accessible IVD project

Capacity Building and Training Activities for AHWP Member Economies and Other Developing Countries

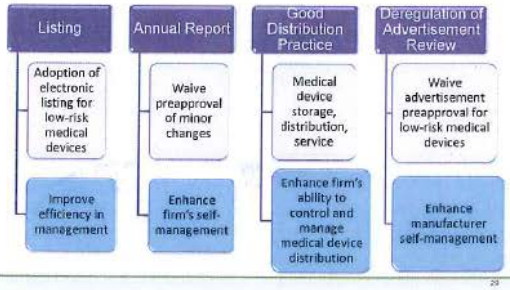
- AHWP WG1a Working Meeting, May 15-16, 2013
- The 1st African Regulatory Forum for Medical Diagnostics & Pre-Forum Workshop, Jul 24-26, 2013
- The AHWP WG1a-PAHWP-LSHTM Joint Conference on International IVD Medical Devices Regulations, Sep 16-18, 2013

Future Initiatives

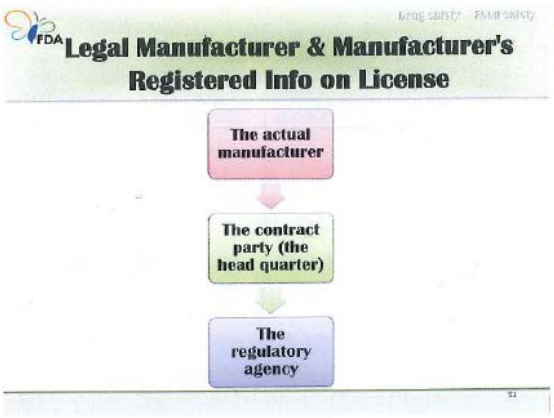
Prospects



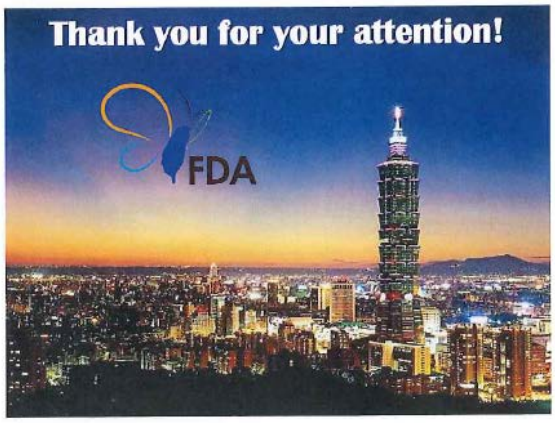
Key Amendments for the Pharmaceutical Affairs Act



Challenges


Drug safety Food safety
Legal Manufacturer & Manufacturer's Registered Info on License
The actual manufacturer
The contract party (the head quarter)
The regulatory agency


Drug safety Food safety
Innovative Organization
Legal Framework
Quality System Management
Pre-market Registration
CONSUMER PROTECTION
International Cooperation
Distribution Management
Consultations & Training
Post-market Surveillance
Increase administrative efficiency


Thank you for your attention!
FDA