出國報告(出國類別：出席國際會議)

出席亞太經濟合作(APEC)法規協和指導委員會(RHSC)會議

服務機關：衛生福利部食品藥物管理署

姓名職稱：黃琴嘵簡任技正

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林奕汝副研究員

林賢一高級審查員

派赴國家：視訊會議

會議期間：**110** 年 **10** 月 **26** 日

報告日期：**110** 年 **12** 月 **15** 日

摘要

衛生福利部食品藥物管理署(以下簡稱食藥署)代表我國長期參與亞太經濟合作(APEC)生命科學創新論壇(LSIF)及其下之次級論壇(RHSC)，同時出席每年 APEC 第一次資深官員會議(SOM1)及第三次資深官員會議(SOM3)期間召開之相關會議。然而因新型冠狀肺炎(COVID-19)疫情影響全球，今(2021)年 APEC 相關會議均以視訊模式召開。本署為 APEC RHSC 中「優良查驗登記管理(GRM)」優先工作領域(PWA)主導經濟體，亦是 GRM 法規科學訓練卓越中心(CoE)主辦機構，於今年 10 月 26 日會議中代表 GRM PWA 向 APEC 各經濟體報告 GRM PWA 未來工作規劃，以及 GRM CoE 培訓成果。本署與各 APEC RHSC 經濟體代表維繫密切良好的互動，同時也積極發聲討論，提案和演講皆獲各國代表的支持與肯定。

關鍵字：亞太經濟合作、生命科學創新論壇、法規協和指導委員會、優良查驗登記管理、法規科學訓練卓越中心、優先工作領域

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壹、目的

本次出席由 APEC 生命科學創新論壇(LSIF)-法規協和指導委員會(RHSC)召開之視訊會議，有下列主要目的：

一、與日本 MHLW/PMDA 召開 GRM 優先工作領域(PWA)共同主導經濟體會前會，討論本次會議簡報內容以及本年度 GRM PWA 工作規劃與成果。

二、於 RHSC 會議報告今年度 APEC GRM PWA 目前工作進度(包含修改 GRM 路徑圖與核心課綱進度)和未來規劃、本署和泰國食品藥物管理局(Thai FDA)召開之「APEC GRM 法規科學訓練卓越中心(CoE)」成果。

三、即時了解 RHSC 的最新進展及未來規劃。

貳、會議行程表

RHSC Oct 2021 Virtual Meeting Agenda

26 Oct 2021, 07:00 – 09:00 Washington DC (GMT-4) / 20:00 – 22:00 Tokyo (GMT+9)

RHSC Oct 2021 Virtual Meeting **26 Oct 2021, 07:00 – 09:00 Washington DC (GMT-4) / 20:00 – 22:00 Tokyo (GMT+9)**
RHSC Welcome and Introductory Remarks (5 mins) Speakers: Dr Nobumasa NAKASHIMA and Dr Michelle LIMOLI, RHSC Co-Chairs
LSIF Advisor's Office Update (10 mins) Speakers: Ms Patricia WU Background Document 1.0
AHC Update (5 mins) Speaker: Dr. Young-Ju CHOI Background Document 2.0
Update from RHSC Co-Chairs (10 mins) Speakers: Dr Nobumasa NAKASHIMA and Dr Michelle LIMOLI, RHSC Co-Chairs Background Documents 3.0-A, 3.0-B, 3.0-C, 3.0-D
Good Registration Management (10 mins total) (Co-Champions: Chinese Taipei – TFDA and Japan – MHLW/PMDA) Background Documents 4.0-A, 4.0-B
PWA Update Speaker: Ms Chyn-Liang HUANG, TFDA Background Document 4.1

CoE Update: TFDA with RAPS Taiwan Chapter Speaker: Ms Chyn-Liang HUANG Background Document 4.1
CoE Update: Food & Food Drug Administration, Thailand (Thai FDA) Speaker: Ms Unsanee RATTANACHEEVAKUL Background Document 4.1
Multi-regional Clinical Trials and Good Clinical Practices Inspection (5 mins total) (Champions: Japan – MHLW/PMDA and Thailand – Thai FDA) Background Documents 5.0-A, 5.0-B, 5.0-C
PWA Update Speaker: Mr Hayato ISHIDA, PMDA Background Document 5.1
Global Supply Chain Integrity (5 mins total) (Champion: US – FDA) Background Document 6.0
PWA Update & CoE Update: United States Pharmacopeia (USP) Speakers: Dr Leigh VERBOIS, US FDA & Mr Michael SCHMITZ, USP Background Document 6.1
Advanced Therapy Products (5 mins total) (Champions: Singapore – HSA and US – FDA; Sub-Champion: BIO) Background Documents 7.0-A, 7.0-B

PWA update Speaker: Dr Srinivasan KELLATHUR, HSA Background Document 7.1
CoE Update: United States Pharmacopeia (USP) Speaker: Dr Maura KIBBEY Background Document 7.2
Biotherapeutic Products (5 mins total) (Current PWA Management: US FDA and BIO Coalition) Background Document 8.0
PWA Update Speaker: Dr Michelle LIMOLI, US FDA Background Document 8.1
CoE Update: Northeastern University (NEU) (updates for both Biotherapeutic Products and Advanced Therapy Products PWAs) Speaker: A/Prof Jared AUCLAIR Background Document 8.2
Pharmacovigilance (5 mins total) (Champion: Korea – MFDS) Background Documents 9.0-A, 9.0-B

PWA Update Speaker: Ms In Sun LEE Background Document 9.1
Medical Devices (5 mins total) (Champions: Korea – MFDS, Japan – MHLW/PMDA and US FDA; Sub-Champions: AdvaMed and JIRA) Background Documents 10.0-A, 10.0-B
PWA Update Speaker: Ms Michelle NOONAN, US FDA Background Document 10.1
WHO Update (5 mins) Speaker: Dr Samvel AZATYAN Background Document 11.0
APEC LSIF Rare Disease Network (5 mins) Speaker: Mr Eric OBSCHERNING, LSIF Advisor's Office Background Document 12.0
Review Decisions and Action Items (5 mins) Lead by RHSC Co-Chairs
Concluding Remarks and Adjourn (2 mins) Lead by RHSC Co-Chairs

參、內容摘要

一、背景說明

亞太經濟合作會議(Asia-Pacific Economic Cooperation, APEC)為目前亞太區最大的經貿合作平台，有 21 個會員經濟體。我國以中華台北(Chinese Taipie)名義參與，屬於正式會員。而 APEC 於 2002 年成立由產官學三方參與之「生命科學創新論壇(Life Science Innovation Forum, LSIF)，以開創對生命科學創新和精進有利之政策環境和對話平台，同時也研提相關發展策略。

有鑑於法規協和(Regulatory Convergence)對生命科學創新的重要性，於 2008 年成立法規協和指導委員會(Regulatory Harmonization Steering Committee, RHSC)，其目標為促進 APEC 區域內醫藥品法規協和。目前 RHSC 主席(Co-Chairs)為美國 FDA 的 Dr. Michelle Limoli 及日本 PMDA 的 Dr. Nobumasa Nakashima，副主席(Vice-Chair)為中國藥學會副秘書長 Ms. Li He。RHSC 下設有 7 個優先工作領域(Priority Working Area, PWA)，分別為 Good Registration Management (GRM) 、Multi-Regional Clinical Trials & Good Clinical Practice Inspection (MRCT-GCP)、Biotherapeutic Products、Global Supply Chain Integrity、Advanced Therapy、Pharmacovigilance 及 Medical Devices，由不同 APEC 會員經濟體醫藥品主管機關擔任主導經濟體(Champion Economy)負責推動。而每個 PWA 下有經 RHSC 認可的法規科學訓練卓越中心(CoE)負責辦理法規人才培訓，期望透過交流培訓達成 APEC 區域間醫藥品法規協和。RHSC 各 PWA 主辦經濟體及 CoE 清單如附件 1。

食藥署(下稱本署)為 RHSC 創始會員，自 2011 年起指導優良審查規範(GRevP)路徑圖，2014 年起與日本合作推動優良送審規範(GSubP)。RHSC 則於 2016 年認可「優良審查規範(GRevP)」及「優良送審規範(GSubP)」合併為「優良查驗登記管理(GRM)」，本署與日本厚生勞動省與醫藥品醫療機器綜合機構(MHLW/PMDA)為 GRM PWA 之共同主導經濟體(Co-Champion)。而為推動 GRM 法規科學訓練及理念，本署與美國醫療法規學會台灣分會(RAPS Taiwan Chapter)於 2017 年聯名獲 RHSC 認可，成為「APEC GRM 法規科學訓練卓越中心(CoE)」，定期舉辦法規科學培訓活動。RHSC 每年於 APEC 第一次資深官員會議(SOM1)及第三次資深官員會議(SOM3)期間召開一次會議，檢視各

PWA(包含 CoE)的推動進展與相關成果。

二、RHSC 線上會議內容

1. 生命科學創新論壇(LSIF)工作報告(LSIF Advisor's Office Update)：

因 RHSC 係屬 LSIF 下次級論壇，故 LSIF 顧問辦公室(Advisor's Office)的 Ms. Patricia Wu 報告 LSIF 工作進度。今(2011)年年初 LSIF 代表們採認「RHSC 2030 願景與策略架構(RHSC 2030 Vision & Strategic Framework)」，並於 8 月 17-18 日召開第 19 屆線上會議及 8 月 24 日召開衛生與經濟高階視訊會議(HLM11)。HLM11 會上產出聯合宣言，將持續關注議題如 regulatory convergence, reliance for medical products review, 對抗 COVID-19 疫情等。

承上，有關「RHSC 2030 願景與策略架構(RHSC 2030 Vision & Strategic Framework)(附件 2)，旨在加速 APEC 區域醫藥品法規協和以守護大眾健康、加速醫藥品上市、培育法規科學人才並強化各經濟體合作交流。達成目標願景之策略有三個方向：(1)在 APEC 經濟體藥政主管機關間達成醫藥品的法規協和(Facilitate regulatory cooperation among medical product regulatory authorities)。(2)培育醫藥品法規科學人才(Build human capacity in regulatory science among medical product regulatory staff)。(3)促進各經濟體醫藥品法規上之合作和互信(Promote political will for convergence and reliance among regulatory policymakers)。

而明(2022)年 APEC 主辦經濟體泰國，將聚焦在持續促進經濟體間發展平衡與成長、投資與創新、重新連結和包容性及永續成長。泰國亦致力於明年召開實體面對面會議。

因 LSIF 將於今年底年屆期，面臨論壇日落(Sunset)，而是否展開 LSIF 任務延續及更新章程(mandate)，抑或是與 HWG 論壇合併，將持續與各經濟體代表討論任何可能。

2. APEC Harmonization Center 報告(AHC Update)：

韓國 APEC Harmonization Center (AHC)報告在今(2021)年所召開的相關培訓活動，以及每一場研討會/訓練活動滿意度與回饋意見。同時也呼籲有意願申請

AHC 贊助(AHC-Funding)召開的研討會的 APEC 經濟體於期限內提出申請。

3. RHSC 主席報告論壇工作進度(Update from RHSC Co-Chairs)：

因應各 PWA 推廣法規協和之路徑圖(Roadmap)將告一段落，RHSC 提供新模板(Template)，鼓勵各 PWA 主導經濟體使用新模板更新路徑圖，並因應新階段制定關鍵績效指標(KPIs)。另，主席們也建議各主導經濟體在制定 KPIs，應朝向「簡短、1-2 個問題、易於回答且能夠測量出進展(Measurable-show progress)」的方向規劃。

此外，多個 CoE 與 LSIF 簽署之合作備忘錄(MoU)將於明(2022)年陸續屆期，為讓 PWA 主導經濟體了解 CoE 過去執行成果及評估是否延續任務，RHSC 提供各即將屆期 CoE「評估工具表(CoE Assessment Report)」(附件 3)，請有意展延 MoU 的 CoE 依據工具表提交相關資料予 PWA CoE 指導委員會(PWA CoE Steering Committee)，而指導委員會將檢視 CoE 成果並給予意見。而本署與 RAPS 台灣分會聯名主辦之 GRM CoE 也將於明(2022)年 7 月 20 日屆期。

4. Good Registration Management (Champions: Chinese Taipei-TFDA and Japan-MHLW/PMDA)

優良查驗登記管理的共同主導經濟體為本署及日本 MHLW/PMDA，目前有 2 個正式法規科學訓練卓越中心(CoE)，分別是本署及泰國醫藥品管理局(Thai FDA)。

本署於會上提供工作簡報(附件 4)，內容聚焦於 GRM PWA 今年工作成果與未來規劃，以及兩個 GRM CoE 辦理研討會成果。本署由黃琴喨簡任技正代表報告。

有關 GRM PWA 今年工作成果，本署於 5 月 20 日主導召開 GRM PWA 指導委員會(Steering Committee)會議，與來自日本 PMDA、JPMA、泰國 FDA、前美國 FDA、IRPMA 等跨單位專家團，討論初步修正 GRM 路徑圖與核心課綱方向，在會上也分享 GRM 及 GSubP 兩份問卷調查分析結果。另，今年本署亦將 GRM 問卷結果與於 APEC 區域推行 GRM 理念之成果撰擬成論文(題目：The Implementation of the 2020 Roadmap to Promote Good Registration Management (GRM) in APEC region)並成功投稿於 Therapeutic Innovation & Regulatory Science

國際期刊中。而有關 GRM PWA 未來規劃，則是預計在年底前(12 月 3 日)召開第二次指導委員會會議，接續討論 GRM 路徑圖、核心課綱與關鍵績效指標之研定。

有關本署於 110 年 8 月 24 日至 9 月 16 日舉辦之「2021 年 APEC GRM CoE 國際研討會」，因受 COVID-19 疫情影響，不同於往年的實體會議，採去實體與混合模式召開。會前為籌備研討會及設計議程，本署召集跨單位之產官學界專家組成「GRM 課程委員會(Program Committee)」，並於 4 月 23 日討論今年研討會議程與講師邀約事宜。今年研討會分為兩個部分，第一部分是邀請預錄講師課程後放在網站上，供學員線上學習；另一部分則是三天線上會議，將學員分為小組進行案例討論，以及邀請來自各藥政主管機關代表演講。研討會總共邀請來自各藥政主管機關及產學界專家如歐盟 EMA、日本 PMDA、澳洲 TGA、APAC、IRPMA 等)共 17 位專家演講或帶領討論，此次也培訓來自 APEC 12 個經濟體共 69 位法規科學人才。而此次學員對研討會整體滿意度非常高，同時也給予諸多正向回饋，提供許多未來本署在推行 GRM 理念和工作時可參考的建議。

此外，泰國 FDA 是 GRM PWA 於去(2020)年正式成為繼本署之後第二個正式 GRM CoE。而泰國 FDA 也於今年召開 1 場線上研討會，同時也預計於明年 7-8 月召開另一場 GRM 研討會。

5. Multi-Regional Clinical Trials and Good Clinical Practices Inspection (Champions: Japan – MHLW/PMDA and Thailand – Thai FDA)：

多區域臨床試驗及優良臨床規範稽查(MRCT-GCP Inspection)共同主導經濟體為泰國 FDA 和日本 MHLW/PMDA，目前正式的法規科學訓練中心有 5 個機關，分別是中國北京大學、日本 PMDA、韓國 KoNECT、新加坡 Duke-NUS 醫學院及美國 MRCT Center of Brigham and Women's Hospital and Harvard。

日本 PMDA 代表報告 MRCT-GCP Inspection PWA 工作成果與進度，在今年中國北京大學、日本 PMDA 及韓國 KoNECT 召開線上或線上實體混合式研討會/會議，同時也草擬套用新模板的路徑圖。此外，有鑑於中國北京大學、新加坡 Duke-NUS 及日本 PMDA 的 CoE 將於明年屆期，目前僅有日本 PMDA 提出展延 CoE 任

期之要求。

另，除新加坡 Duke-NUS 外，其餘 CoE 於明年皆有計畫召開相關培訓課程或研討會。

6. Global Supply Chain (Champion: US FDA)：

全球供應鏈完整性的主導經濟體是美國，由美國 FDA 負責，目前有 3 個正式 CoE，分別為美國 USP、University of Tennessee Health Science Center 以及馬來西亞 Taylor's University。

全球供應鏈 PWA 將於今年 11 月的 APEC 部長級會議報告其調查各藥政主管機關、業界對於預防偽劣藥進入供應鏈所做的努力和行動。此外，今年指導委員會將專注於更新上市後安全監測(Post-Market Surveillance)以及網路銷售(Internet Sales)的工具(Toolkits)。上市後安全監測之工作將專注於產官學各界共同致力於疫情下上市後藥品的監督，工具(Toolkit)預計於明年初更新完畢。而網路銷售部分則會呼籲各界於疫情下更應致力於打擊偽劣 COVID-19 疫苗，近期將會籌組工作組來檢視這部分的資料。

另，美國 USP 及馬來西亞 Taylor's University 均於今年召開全球供應鏈研討會。

7. Advanced Therapy Products (Champions: Singapore-HSA/ US-US FDA)：

先進醫療產品的主導經濟體是新加坡與美國，由新加坡 Health Sciences Authority (HSA)與美國 FDA 負責。目前有 3 個正式 CoE，分別為美國 USP、美國東北大學(Northeastern University)以及新加坡 Duke-NUS 醫學院。

美國 USP 已於今年 5 月成為正式的 CoE，同時也預計明年初於南美召開 Biotherapeutics, cell and gene therapy 人才培訓活動。同時，預計於今年底前完成召開先進醫療產品 PWA 指導委員會，討論更新路徑圖乙事。

8. Biotherapeutic Products (Current PWA Management: US FDA and BIO Coalition)：

目前無正式主導經濟體與負責單位，現階段由美國 FDA 暫時擔任主導經濟體，而 Sub-Champion 則為業界代表 BIO 聯盟。美國 FDA 及 BIO 則會在今明兩年暫時擔任主導單位直到有正式的主導經濟體出現。而 Biotherapeutics 經濟體

底下有 2 個正式與 1 個先期(Pilot) CoE，正式 CoE 分別為日本神戶大學(Kobe University)及美國東北大學(Northeastern University)，而 Pilot CoE 則為新加坡 Duke-NUS 醫學院。

今年僅有日本神戶大學召開 Biotherapeutic Products 的線上研討會，而美國東北大學則預計於明年初召開。Duke-NUS 醫學院則繼續延後辦理先期(Pilot) CoE 訓練活動。另，暫時主導經濟體們預計於年底前召開會議討論路徑圖的修正。

9. Pharmacovigilance (Champion: Korea-MFDS)：

藥品安全監視的主導經濟體是韓國，由韓國食品醫藥品安全處(MFDS)負責。目前有 3 個正式 CoE，分別是中國北京大學、日本 MHLW/PMDA 以及韓國藥物安全與風險管理機構(KIDS)。

三個 CoE 於今年均辦理線上研討會。而有鑑於 PMDA 之 PV CoE 將於明年屆期，日前 PMDA 已提交 CoE 成果評估報告，欲展延 CoE 的任期。

10. Medical Device (Champions: Korea-MFDS, Japan-MHLW/PMDA；Sub-Champion: AdvaMed and JIRA)

醫療器材的主導經濟體是韓國、日本及美國，分別由韓國食品藥品安全處(MFDS)、日本 MHLW/PMDA，協辦單位則為日本 JIRA (Japan Medical Imaging and Radiological Systems Industries)及美國 Advanced Medical Technology Association (AdvaMed)。目前有 6 個正式 CoE 及 2 個先期(Pilot) CoE，正式的 CoE 分別為中國四川大學(Sichuan University)、日本 PMDA、韓國國立醫療器材安全資訊處(NIDS)、韓國 Soonchunhyang 大學、本署(TFDA)及美國南加大(USC)。而 Pilot CoE 則有 2 個，分別是新加坡 Duke-NUS 醫學院以及美國東北大學(Northeastern University)。

本署、中國四川大學與韓國 NIDS 及 Soonchunhyang 大學均於今年召開線上藥品安全監視(PV)研討會。而在醫療器材的 PWA 指導委員會中，討論因醫療器材上尚屬初步發展階段，故也決議非醫療器材核心課綱之內容不建議作為 CoE 研討會課程內容。

11. 世界衛生組織(WHO)報告：

WHO 法規協和網絡(Regulatory Convergence and Networks)主管 Dr. Samvel Azatyan 報告，WHO 對於促進法規體系強韌、和諧與協同所採取的行動和策略。WHO 自 2019 年以來執行為期 4 年的行動計畫以提升醫藥品的品質和安全。此外，亦透過 4 大策略來促成健康全面覆蓋(Universal Health Coverage, UHC)，分別為：

(1) 強化區域與國家體系鏈結以促進健康全面覆蓋 (Strengthen country and regional systems in line with the drive toward UHC)

(2) 增進對於因應緊急衛生情形的準備 (Increase regulatory preparedness for public health emergencies)

(3) 強化及拓展 WHO PQ 及醫藥品風險管理措施 (Strengthen and expand WHO prequalification and product risk assessment process)

(4) 促進 WHO 在提升法規量能活動的影響力 (Increase the impact of WHO's Regulatory Supportive activities)

12. APEC LSIF 罕見疾病網絡(Rare Disease Network)：

由 APEC LSIF 顧問辦公室的 Mr. Eric Obscherning 報告罕見疾病網絡(Rare Disease Network, RDN)工作進度和規劃。Mr. Obscherning 分享 RDN 近年的規劃和遠景，並尋求未來與各 PWA 合作機會。

13. 會議討論事項和結論(Review Decisions and Action Items)：

RHSC 主席美國 FDA 的 Dr. Michelle Limoli 及日本 PMDA 的 Dr. Nobumasa Nakashima 宣達以下事項：

(1) RHSC 主席們請各 PWA 主導經濟體著手修正路徑圖(Roadmap)與核心課綱，同時也鼓勵制定新的關鍵績效指標(KPIs)以評估 PWA 在推廣法規協和(Regulatory Convergence)。另，RHSC 主席亦要求新修正的路徑圖與相關資料須於明(111)年 1 月中前提交。

(2) 有鑑於部分 CoE 將於明(111)年屆期，RHSC 主席請各 PWA 詢問其下之 CoE 是否有意展延(Renewal)任期(MoU)5 年。如 CoE 有意願，RHSC 請各 PWA 主

導經濟體依循「CoE 評估工具(CoE Assessment Tool)」審查 CoE 工作成果。另，RHSC 主席建議 CoE 任期展延作業應於 MoU 屆期前 1-2 個月完成。

14. 本次 APEC RHSC 線上會議之會議紀錄(由 RHSC 秘書處提供)如附件 5。

肆、心得與建議

一、持續關注 APEC LSIF 及 RHSC 動向，確保本署能持續在藥政管國際場域上保有一席之地。

有鑑於 LSIF 及 RHSC 將於 2021 年年底屆期，近期各 APEC 經濟體積極討論是否再延續 LISF 任務 4 年。而 RHSC 身為 LSIF 底下次級論壇，是否存亡亦受 LSIF 展延影響。然 LSIF 展延與否存有極高不確定性，故建議如 LSIF 未能延續且 RHSC 不復存在，應思考未來因應策略，確保本署能夠延續原先已在 APEC RHSC 所保有的一席之地及在 GRM PWA 主導經濟體的優勢。現階段初步思考因應策略如下：

1. 本署與日本 MHLW/PMDA 為 GRM PWA 主導經濟體，而本署亦為 GRM CoE 主辦機構，故除對於 GRM PWA 未來規劃走向有話語權，同時也可透過辦理培訓課程，將規劃實踐和執行。另，也能透過辦理 GRM 培訓活動，累積與國際藥政主管機關和產業界之人脈網絡，尋求未來合作交流機會。所幸過往(2016-2021)年 APEC GRM 國際研討會均由本署自費辦理，即便未來 RHSC 不再延續而本署亦不能以「GRM CoE」名義召開培訓活動，仍可善用過往在 APEC 場域累積的師資/學員人脈和辦理經驗，持續召開相關會議。
2. 此外，如少了 RHSC 這個平台拓展人脈，那未來勢必要更強化聯繫現有在 APEC RHSC 和 GRM 累積的人脈網絡，像是建立完善的人脈資料庫、多加關注各藥政主管機關舉辦研討會和關注之新興議題等。實需與產官學界專家保持良好的互動，以確保未來如 APEC 底下有新論壇產生時可佔得先機，同時也應尋求更長期穩定的合作機會。

二、為持續推廣 GRM 理念，應確保推行方向與國際接軌。

考量本署與日本 MHLW/PMDA 合作推廣 GRM 理念多年，GRM 路徑圖在 2011-2020 年間取得一定程度的成果，而近期 RHSC 主席亦請各 PWA 主導經濟體思考未來推行方向並修改路徑圖。本署於近期也與 GRM PWA 指導委員會(Steering Committee)之跨國、跨機構專家團隊研擬路徑圖之修正。故為能持續在 APEC 區域推行 GRM 理念，倡導優良審查規範(Good Review Practice, GRevP)及優良送件規範(Good

Submission Practice, GSubP)，新版 GRM 路徑圖應扣合國際上各藥政主管機關有共識的推行方向(如扣合 RHSC 或者 LSIF 長期願景)，同時也應保有彈性，能即時納入國際新興關注議題(如 COVID-19 疫情)，確保路徑圖內容與時俱進。

三、**應透過完善和精進課程內容與講師以區隔本署和泰國 FDA 主導之 GRM CoE 培訓活動，維持我國於 GRM CoE 下引導地位。**

除本署外，泰國 FDA 於去(109)年獲 RHSC 採認成為繼本署之後第二個 GRM CoE。考量我國與泰國地域性區別不大，且辦理時程接近，勢必要採取其他策略，以區隔兩者之定位。建議策略如下：

1. 精進研討會課程內容：
   (1) 就往年本署辦理 GRM 研討會學員回饋，來自東協經濟體學員多有建議可以設計「學名藥查驗登記相關課程」，而從今(110)年泰國研討會課程亦聚焦於 GRM 核心課綱之基礎課程與學名藥議題。考量東協各藥政主管機關需求，加上泰國有地利和語言文化之便，本署應另闢關注議題，以確保定位區隔。
   (2) 辦理研討會不僅為弭平 APEC 區域間法規落差，更應提升我國藥政專業，爰建議未來於 GRM 課程中納入新興關注議題，如 Biosimilar、orphan drugs、RNA and DNA-based vaccines、next generation vaccines、目前 RHSC 2030 Vision 與 WHO 關注之 reliance 或 work-sharing、我國推行倡議 Digital Health 等。
2. 不侷限於 APEC 區域，善用所有資源：
   (1) 在新興關注議題中可洽詢非 APEC 經濟體之專家，請其分享經驗。如今(110)年 8-9 月 APEC GRM 國際研討會，為了解 ACCESS(英國、澳洲、瑞士、加拿大、新加坡等國)審查合作機制，亦洽詢非往年合作的單位。
   (2) 此外，雖 RHSC 宗旨在於調和 APEC 經濟體間法規，然隨著時間推移國際間邊界愈趨模糊，也愈多非 APEC 經濟體對 GRM 議題表達興趣。故將 GRM 研討會資訊轉知更多單位，可望吸引更多不同單位、背景的法規人員。

附件 1、RHSC 各 PWA 主辦經濟體及 CoE 清單

Advanced Therapy Products	
Champion(s)	**CoE (Formal/Pilot)**
◆ Health Sciences Authority (HAS), Singapore ◆ US Food and Drug Administration (FDA), United States ◆ Biotechnological Innovation Organization (BIO)	**[Formal]** ◆ Duke-NUS Medical School, Singapore ◆ Northeastern University, United States ◆ United States Pharmacopeia (USP), United States
Biotherapeutic Products	
Champion(s)	**CoE (Formal/Pilot)**
◆ US Food and Drug Administration (FDA), United States ◆ Biotechnological Innovation Organization (BIO)	**[Formal]** ◆ Kobe University, Japan ◆ Northeastern University, United States **[Pilot]** ◆ Duke-NUS Medical School, Singapore
Global Supply Chain Integrity	
Champion(s)	**CoE (Formal/Pilot)**
◆ US Food and Drug Administration (FDA), United States	**[Formal]** ◆ Taylor's University, Malaysia ◆ The University of Tennessee Health Science Center (UTHSC), United States ◆ United States Pharmacopeia (USP), United States

Medical Devices	
Champion(s)	**CoE (Formal/Pilot)**
◆ Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA), Japan ◆ Ministry of Food and Drug Safety (MFDS), Korea ◆ US Food and Drug Administration (FDA), United States Sub-Champions ◆ Japan Medical Imaging and Radiological Systems Industries Association (JIRA) ◆ Advanced Medical Technology Association (AdvaMed), United States	**[Formal]** ◆ Sichuan University (SCU), China ◆ Pharmaceutical and Medical Devices Agency (PMDA), Japan ◆ National Institute of Medical Device Safety Information (NIDS), Korea ◆ Soonchunhyang University (SCH), Korea ◆ Taiwan Food and Drug Administration (TFDA), Chinese Taipei ◆ University of Southern California (USC), United States **[Pilot]** ◆ Northeastern University (NEU), United States ◆ Duke-NUS Medical School, Singapore
Good Registration Management (GRM)	
Champion(s)	**CoE (Formal/Pilot)**
◆ Taiwan Food and Drug Administration (TFDA), Chinese Taipei ◆ Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical	**[Formal]** ◆ Taiwan Food and Drug Administration with Regulatory Affairs Professionals Society (RAPS) Taiwan Chapter, Chinese Taipei ◆ Food and Drug Administration,

Devices Agency (PMDA), Japan	Thailand
Multi-Regional Clinical Trial & Good Clinical Practice Inspection	
Champion(s)	**CoE (Formal/Pilot)**
◆ Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA), Japan ◆ Food and Drug Administration, Thailand (Thai FDA)	**[Formal]** ◆ Peking University (PKU), China ◆ Pharmaceutical and Medical Devices Agency (PMDA), Japan ◆ Korea National Enterprise for Clinical Trial (KoNECT), Korea ◆ Centre of Regulatory Excellence (CoRE), Duke-NUS Medical School, Singapore ◆ The MRCT Center of Brigham and Women's Hospital and Harvard (MRCT Center), United States
Pharmacovigilance	
Champion(s)	**CoE (Formal/Pilot)**
◆ Ministry of Food and Drug Safety (MFDS), Korea	**[Formal]** ◆ Peking University, China ◆ Pharmaceutical and Medical Devices Agency (PMDA), Japan ◆ Korea Institute of Drug Safety and Risk Management (KIDS), Korea

附件 **2**、**RHSC 2030** 願景與策略架構 **(RHSC 2030 Vision & Strategic Framework)**

Asia-Pacific Economic Cooperation Life Sciences Innovation Forum (APEC LSIF)

Regulatory Harmonization Steering Committee (RHSC)

Vision 2030

&

Strategic Framework

Regulatory Convergence for Medical Products by 2030

1. Background

The Asia-Pacific Economic Cooperation (APEC) Life Sciences Innovation Forum (LSIF) and its Regulatory Harmonization Steering Committee (RHSC) adopted its strategic plan (*Vision 2020: A Strategic Framework: Regulatory Convergence for Medical Products by 2020*) in 2010 in Sendai, Japan. This strategic plan provided the basic proposal and rationale for achieving regional regulatory convergence of medical product approval procedures, which APEC Ministers reiterated in the Joint Ministerial Statement in 2011. While each APEC member economy adopted each phase on its own timeframe, the ultimate aim was for APEC economies to achieve as much regulatory convergence as possible by 2020.

Since 2010, the RHSC has facilitated a number of major accomplishments including but not limited to:

- Establishment of seven (7) Priority Work Areas (PWAs) including:
    - Multi-Regional Clinical Trials (MRCT) + Good Clinical Practices (GCP) Inspection;
    - Good Registration Management (GRM);
    - Pharmacovigilance;
    - Global Supply Chain Integrity;
    - Biotherapeutics;
    - Advanced Therapies; and,
    - Medical Devices;

- Implementation of a PWA Roadmap in all seven (7) PWAs to define the key issue and its importance, identify gaps in capacity, prioritize needs, develop a strategic program to close those gaps, and evaluate progress along the way;

- Establishment of 24 pilot and formal APEC Training Centers of Excellence for Regulatory Science (CoEs) at 16 host institutions across nine (9) APEC economies in all seven (7) PWAs to build skilled human capacity, promote dialogue with a view towards sharing understanding in science and best practices, achieve a model of sustainable operation, and avoid duplication of efforts;

- Development and maintenance of a Core Curriculum in all seven (7) PWAs containing the required elements based on relevant international standards and guidelines from the Roadmap that are needed in order to meet the training objectives of the CoEs;

- Establishment and monitoring of eleven (11) key performance indicators (KPIs) (*see original paper*) to measure and visualize progress towards achieving regulatory convergence for pharmaceutical products over the last decade and on an annual basis, including:
    - Number of economies engaging in information sharing;
    - Number of economies establishing confidentiality commitments;
    - Number of economies accepting PIC/S Good Manufacturing Practices (GMP) certificates to reduce the inspection burden;
    - Number of economies establishing Mutual Recognition Agreements (MRAs);
    - Number of economies minimizing required Certificates of Pharmaceutical Product (CPPs);
    - Number of economies allowing multiple sites in a single license;
    - Number of economies utilizing reliance practices in the regulatory evaluation;
    - Number of economies utilizing reliance practices to waive secondary quality control testing;
    - Number of economies in the International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH);

- Number of economies in the International Pharmaceutical Regulators Programme (IPRP);
- Number of economies in the Pharmaceutical Inspection Co-operation Scheme (PIC/S); and,

- Establishment and monitoring of eight (8) key performance indicators (KPIs) to measure progress towards achieving regulatory convergence for medical devices over the last decade and on an annual basis, including:
  - Number of economies in the International Medical Device Regulators Forum (IMDRF);
  - Number of economies in the Asian Harmonization Working Party (AHWP);
  - Number of economies in the APEC RHSC;
  - Number of economies accepting IMDRF Medical Device Single Audit Program reports;
  - Number of economies establishing MRAs;
  - Number of economies implementing IMDRF/GHTF premarket documents;
  - Number of economies implementing IMDRF/GHTF postmarket documents; and,
  - Number of economies implementing IMDRF/GHTF quality documents.

In August 2019 in Puerto Varas, Chile, the LSIF with support from the APEC Harmonization Center (AHC) organized the *2nd LSIF Policy Dialogue on Innovation, Regulatory Systems, and Regulatory Convergence*. The Policy Dialogue convened the leaders of pharmaceutical and medical device regulatory authorities and representatives from industry and academia to reflect on a decade of progress towards regulatory convergence in APEC and to envision the next iteration of a strategy for achieving regional regulatory convergence of medical product approval procedures by 2030.

2. Purpose

The purpose of this document is to outline a new strategic framework to 2030—a structured method the RHSC will use to define how it supports the key objectives of its stakeholders including regulatory authorities, industry, academia, and scientific organizations. While this strategic framework will establish an updated vision, mission, and set of goals for the RHSC, it will more importantly describe how the RHSC will achieve these core elements, and do so in support of the broader goals of access to medical products, improved public health, and economic development.

The intended audience for this document includes members of the APEC LSIF and APEC LSIF RHSC, including representatives from government, medical product researchers and manufacturers, academia, and scientific organizations; APEC Health Ministers, Trade Ministers, and other Senior Officials; and patients, caregivers, and other end-users of regulated medical products.

3. Strategic Framework

3.1 Vision 2030

Our vision is to accelerate regulatory convergence for medical products in the APEC region as much as possible by 2030 in order to protect people's safety, make life-saving products available, save public resources, attract investment, mitigate corruption, and improve global standing in every APEC economy.

3.2 Mission

Our mission is to facilitate regulatory cooperation among medical product regulatory authorities, build human capacity in regulatory science among medical product regulatory staff, and promote political will for convergence and reliance among regulatory policymakers in APEC.

3.3 Values

Our values describe the individual and organizational behaviors that will enable the RHSC to achieve the mission and live the vision, to accelerate regulatory convergence and reliance.

- Clarity of the course ahead – we value clear goals and strategies, and the practice of horizon scanning to inform decision makers about possible future opportunities and threats.
- Centrality of the community – we value patients, caregivers, and other end-users of the medical products regulated in our economies.
- Calibration by outcomes & indicators – we value measurement of progress and performance, and its importance for communicating the 'why' and 'how' of regulatory convergence.

- Capacity building with strategy & sustainability – we value frontline regulatory staff, and the importance of enabling them long-term to obtain, improve, and retain skills and knowledge.
- Culture of collaboration – we value the opportunity to work together across teams, sectors, and economies toward common goals, and to provide every member with equal opportunity to lead.
- Connection between global, regional & local levels – we value coordination between stakeholders of global and regional initiatives and the member regulatory authorities and welcome their participation.
- Communication with politicians, patients & public – we value dialogue on regulatory convergence among the highest levels of government to the end-users of medical products.
- Commitment to improve – we value the constant pursuit of regulatory convergence, that it is never fully achieved or complete as new science drives novel products and updated regulations.

3.4 Definitions

- **Regulatory convergence** represents a voluntary process whereby the regulatory requirements across economies become more aligned (or more similar) over time as a result of the gradual adoption of harmonized international guidances and standards, and internationally recognized scientific principles, practices, and procedures. It does not seek to establish new or change existing legal frameworks, laws, or regulations. It does not require regulators to be subject to any outside authority or prevent regulatory authorities from protecting and promoting public health. It does not have a specific endpoint; regulatory convergence is never "complete" or "achieved" as new products are developed, new standards are established, and new regulatory staff begin careers.

- **Regulatory reliance** is the act whereby the regulatory authority in one jurisdiction may take into account and give significant weight to – i.e., totally or partially rely upon – evaluations performed by another regulatory authority or trusted institution in reaching its own decision. The relying authority remains responsible and accountable for decisions taken, even when it relies on the decisions and information of others.

3.5 Guiding Principles

- RHSC will adopt a strategic, coordinated approach to regulatory convergence and reliance, and does not seek to develop new guidances or standards.

- While regulatory convergence by definition does not seek to establish new or change existing legal frameworks, laws, or regulations, RHSC may serve as a resource to APEC economies which have decided to establish or change these in pursuit of regulatory convergence and harmonization.

- Participation is voluntary and open to all APEC economies, and decisions are consensus-based.

- RHSC will work to constantly innovate and incubate new ideas to accelerate regulatory convergence building on past successes such as the APEC Training Centers of Excellence for Regulatory Science.

3.6 Goals, Strategies & Tactics

3.6.1 Goal: Facilitate regulatory cooperation among medical product regulatory authorities

A. Strategy: Build neutral platforms for cohesion and alignment

- **Action:** Convene meetings of the RHSC twice per year at the First and Third Senior Officials Meetings and provide space for side-meetings, workshops, and networking
- **Action:** Maintain Priority Work Areas (PWAs) with active PWA Champions[1], and Co-Champions, and PWA Steering Committees to help prioritize specific objectives, organize activities, and create communities
- **Action:** Create virtual spaces for regulatory cooperation through the RHSC website and email distribution lists which are updated at least twice per year

B. Strategy: Build tools for regulatory information-sharing and work-sharing

- **Action:** Provide and, if needed, assist in the development of template agreements and guidelines for information-sharing, work-sharing, memoranda of cooperation, confidentiality commitments, among others
- **Action:** Explore the feasibility of developing a technical platform to facilitate information-sharing and work-sharing between APEC regulatory authorities at scale

C. Strategy: Promote regulatory convergence and reliance and its tools

[1] An RHSC member that leads the organization of activities to promote convergence within a PWA and serves as (1) the primary author of a PWA roadmap, (2) lead advisor to all CoEs within a PWA, and (3) chair of the PWA CoE Steering Committee.

- **Action:** Organize regular workshops to explain and support the use of instruments of reliance including but not limited to sharing Good Manufacturing Practices (GMP) certificates; minimizing Certificates of Pharmaceutical Product (CPP) requirements; establishing Memoranda of Cooperation (MoC), Confidentiality Commitments, and Mutual Recognition Agreements (MRAs); and joining the Medical Device Single Audit Program (MDSAP); among others
- **Action:** Support participation in regulatory harmonization initiatives including but not limited to the International Council on Harmonisation (ICH), International Pharmaceutical Regulators Programme (IPRP), International Medical Device Regulators Forum (IMDRF), and Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S), among others
- **Action:** Explore the feasibility of developing consensus-driven joint APEC commitments and bilateral or multilateral reliance agreements

3.6.2 Goal: Build human capacity in regulatory science among medical product regulatory staff

A. **Strategy:** Strengthen and scale APEC Training Centers of Excellence for Regulatory Science
    - **Action:** Support the Center of Excellence Coalition to promote training activities, nominate participants to attend training activities, and encourage partnerships and collaboration between Centers of Excellence
    - **Action:** Encourage consistent, long-term, and peer-to-peer training and the development of peer networks for participants in person and virtually following Center of Excellence training programs
    - **Action:** Organize *ad-hoc* virtual and in-person workshops for Center of Excellence faculty to exchange information on topics such as innovative training methods
    - **Action:** Enable more regulatory staff from more APEC economies to participate in Center of Excellence training programs by, for example, maintaining a comprehensive database of programs for the upcoming year and sharing information beyond APEC
    - **Action:** Measure the short- and long-term learning outcomes of Center of Excellence programs with both quantitative and qualitative indicators

B. **Strategy:** Maintain strategic roadmaps and core curricula to guide programming
    - **Action:** Review roadmaps every 5 years at a minimum, and core curricula every 2 years at a minimum

3.6.3 Goal: Promote political will for convergence and reliance among regulatory policymakers

A. **Strategy:** Explore new ways to measure regulatory convergence and its impacts
    - **Action:** Continue measuring progress towards regulatory convergence with proxy indicators including but not limited to the number of APEC economies participating in regulatory harmonization initiatives, sharing GMP certificates, etc.
    - **Action:** Analyze the macroeconomic case for and cost of inaction on regulatory convergence and reliance, and promote this information in regional and global fora

B. **Strategy**: Elevate the case for regulatory convergence and reliance, including at the highest political levels
    - **Action:** Issue an annual letter from the RHSC Co-Chairs to the heads of regulatory authorities in APEC economies informing them of progress to date, outlining upcoming plans, and inviting them to participate in RHSC meetings
    - **Action:** Organize policy dialogues to discuss regulatory convergence and reliance with a wider scope of APEC stakeholders, including regulatory policymakers, legislators and parliamentarians, patient organizations, and senior trade and health officials
    - **Action:** Secure continued high-level political support for RHSC in annual statements from APEC Health Ministers, Trade Ministers, and Senior Officials, where applicable
    - **Action:** Position APEC economies as champions of regulatory convergence and share progress with non-APEC economies

C. **Strategy:** Support policymakers seeking to establish or change legal frameworks, laws, or regulations

- **Action:** Organize policy dialogues to discuss regulatory convergence and reliance with a wider scope of APEC stakeholders, including regulatory policymakers, legislators and parliamentarians, patient organizations, and senior trade and health officials
- **Action**: Supply policymakers with guiding principles on decision-making towards the establishment or change of legal frameworks, laws, or regulations, when needed

3.7 Indicators

Goal: Facilitate regulatory cooperation among medical product regulatory authorities in APEC

- Process indicator(s): Number of APEC economies participating in RHSC, PWAs, virtually
- Output indicator(s): Index scores to measure perceived effectiveness of RHSC
- Outcome indicator(s): Existing RHSC KPIs

Goal: Build human capacity in regulatory science among medical product regulatory staff in APEC

- Process indicator(s): Number of hosts, Centers, training programs, faculty/participants
- Output indicator(s): Aggregate participant feedback with before-after training program analysis
- Outcome indicator(s): Pre- and post-training assessment with standard scoring system

Goal: Promote political will for convergence and reliance among regulatory policymakers in APEC

- Process indicator(s): Number of and participation at policy dialogues
- Output indicator(s): Aggregate participant feedback with before-after policy dialogue analysis
- Outcome indicator(s): Revisions to existing domestic legal frameworks, laws, or regulations; time duration of review

3.8 Anticipated Impacts

In working to achieve regulatory convergence and reliance we believe the anticipated impacts include:

- **Protects people's safety:** when economies take advantage of testing, inspections, and reviews already done by high-performing regulators around the region, economies can efficiently ensure

approved products are both effective and safe, and work together to identify and share safety issues in their collective population.

- **Makes products available & promotes access:** when economies leverage the assessment work already done by high-performing regulators on a particular life-saving product, economies can approve that product more quickly and ensure it is readily available on the market to those who need it.

- **Saves public resources:** when economies tap into the expertise and work of other high-performing regulators around the region, economies can avoid unnecessary duplication and limit wasteful spending so economies save precious public health resources for use elsewhere.

- **Attracts investment:** when economies shorten burdensome procedures and adopt best practices by trusting the processes of high-performing regulators, economies can reduce uncertainty and delays so that both local and international firms find it easier to do business in APEC economies, invest their capital, and create jobs.

- **Improves efficiency:** when economies avoid duplicate inspections and lengthy approval procedures, economies can reduce the time it takes to respond to an application

- **Improves global standing:** when economies share the load with other regulators and join international initiatives, economies show their willingness to cooperate and support best practices, which strengthen the global community and enable investment in APEC economies.

附件 3、CoE 評估工具表(Assessment Report)

RHSC Training Center of Excellence (CoE) for Regulatory Science Assessment Plan

Pursuant to Section IV.E.4. of the CoE Operating Model and Guidelines

Draft November, 2020

Assessment Plan

- Every 5 years, each CoE should compile the information outlined in the rubric below, in addition to the CoE's reports to the RHSC from the previous 5 years and a summary of all student evaluations from the previous 5 years (the actual assessments shall be available upon request). If a CoE Host Institution has an endorsed CoE in multiple PWAs, the institution would compile and submit separate assessment packages for each CoE it hosts.

- Once compiled, the CoE Host Institution should send the assessment package(s) to the relevant PWA CoE Steering Committee(s). A **CoE Assessment Committee** composed of the PWA CoE Steering Committee members, RHSC Co-Chairs if not already included, LSIF Advisors, and CoE Coalition Co-Chairs should review the assessment package.

- If the assessment indicates that the program is not effective or not meeting the training objectives, the CoE Host Institution and PWA Steering Committee will collaborate to resolve the issues. If issues cannot be successfully resolved within a reasonable time (to be agreed upon by the parties), either party may choose to exit the MOU.

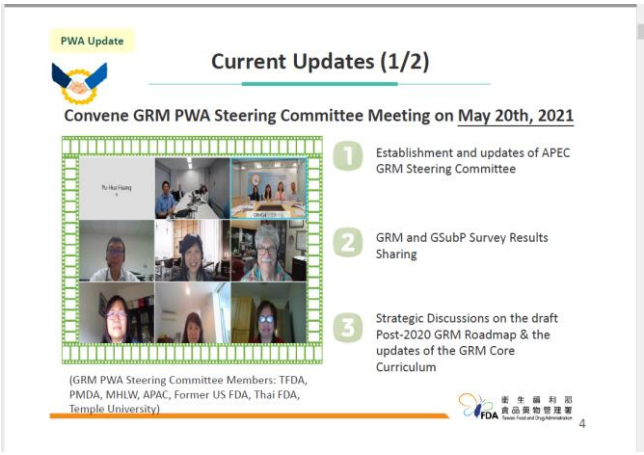
- CoE assessments should seek not only to monitor and evaluate performance, but also to inform strategic adjustments or adaptations to the CoE's approach or programming, as well as the PWA and RHSC's approach writ large (at scale).

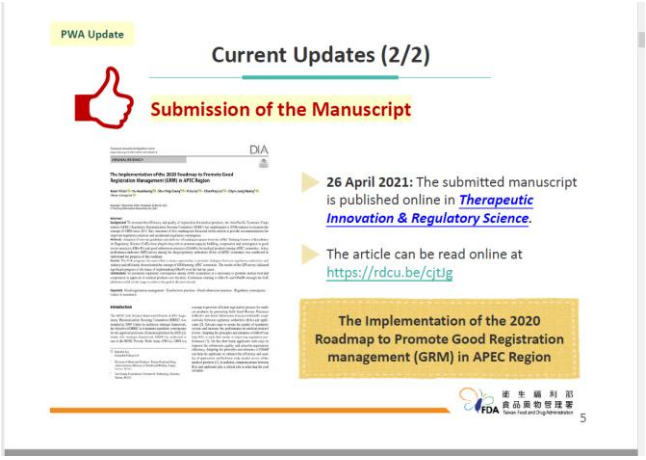
CoE Self-Assessment Rubric (Virtual and In-Person)

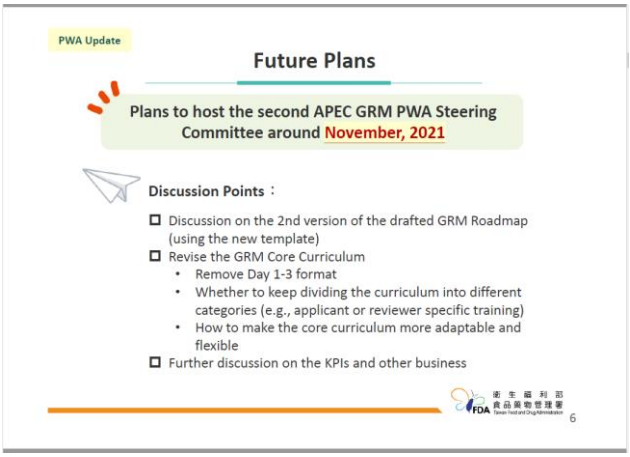
S/N	Parameter	Sub-Parameters / Notes
	Quantitative Measures	
1	Number of Workshops	• Parameters (examples) ○ By PWA ○ In Total ○ Frequency of Workshops ○ By delivery medium (virtual or in-person) *Total number of training workshops held by the COE that is endorsed by APEC RHSC; was a minimal of two trainings held in the last 5 years?*
2	Number of Trainees/Students	• Total Number per Workshop • Breakdown by Economy; number of economies (APEC, non-APEC) • Breakdown by organization type • Breakdown by years of experience • Total Number across all workshops (within a PWA, and across all PWAs)
	Qualitative Measures (Scale 1-3; 1-dissatisfied and 3 satisfied)	
1	Curriculum	• Effectiveness in meeting the training objectives and core curriculum as described in the PWA Roadmap

S/N	Parameter	Sub-Parameters / Notes
2	Student/Trainee Satisfaction	• Percent of students/trainees who are satisfied with the training workshop held by the COE and endorsed by APEC RHSC • Consider use of Net Promoter Score
3	Faculty Satisfaction	• Percent of trainers who are satisfied with the training workshop held by the COE and endorsed by APEC RHSC
4	PWA Champion Satisfaction	• Based on the Sub-Parameters mentioned above, tailored from perspective of the PWA Champion • Evaluation of training program by the PWA and PWA CoE Steering Committee
5	Quality of Faculty	• Biographies of faculty
6	Lessons learned	• List lessons learned from CoE director and evaluation forms
7	Follow-up post training (optional)	• What, if any, measures did the CoE use for follow-up post-training? • Did CoE participants share the information learned with other members of their team?

附件 4、本署 APEC GRM 工作成果與未來規劃簡報







Taiwan Food and Drug Administration Ministry of Health and Welfare

CoEs Update

衛生福利部 食品藥物管理署 Taiwan Food and Drug Administration

http://www.fda.gov.tw/ 7

Taiwan Food and Drug Administration Ministry of Health and Welfare

GRM CoE Workshop by TFDA

衛生福利部 食品藥物管理署 Taiwan Food and Drug Administration

http://www.fda.gov.tw/ 9

GRM Workshop Hosts & Organizers

2021 APEC GRM CoE Workshop

Host

TFDA — RAPS Taiwan Chapter

Co-Organizers

APEC LSIF RHSC — MHLW — PMDA — APAC

Participating Organizations

EMA — TGA — IRPMA — CDE

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Organizing the Workshop

Convene GRM CoE Program Committee Meeting on April 23th, 2021

1. Discussion on the 2021 APEC GRM CoE Workshop Program Draft
2. Updates on the progress of workshop preparation, speakers invitations and future timelines
3. Participating Organizations: TFDA, PMDA, APAC, IRPMA, Thai FDA, Temple University

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Workshop Summary

Schedule & Program	Participants	Speakers & Facilitators	Themes
PART 1: Online Self-Learning Lectures Aug 24th- Sep 24th	Total: 69 participants	17 Speakers (TFDA/CDE/ PMDA/EMA/ TGA/APAC/ IRPMA/ Temple University)	GRM Core Curriculum Sessions
PART 2: Live-videoconferences Sep 14th- Sep 16th	Reviewers: 28 Applicants: 41	10 Facilitators (CDE/IRPMA)	Promoting Regulatory Cooperation
	12 Economies		The Application of RWD/RWE in Regulatory Decision-Making

＊12 Economies: Chinese Taipei, Hong Kong, Indonesia, Japan, Korea, Malaysia, Peru, Philippines, Russia, Singapore, Thailand, Viet Nam

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Workshop Program (1/5)

PART 1: Online Self-Learning Lectures

The GRM CoE Workshop participants could access the website to watch the pre-recorded lectures.

Content 1: Opening Remarks

Dr. Shih-Chung Chen
Minister of the Ministry of Health and Welfare (MOHW)

Dr. Shou-Mei Wu
Director General of TFDA

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Workshop Program (2/5)

GRM Core Curriculum Sessions

Session 1: Introduction of GRM

Ms. Chyn-Liang (Cindy) Huang (TFDA)

Session 2: Planning of Application

Ms. Finny Liu (APAC)/ Ms. Jocelyn Lee (IRPMA)

Session 3: Preparation of Application Dossier

Ms. Kumiko Hikida (APAC)/ Ms. Hiroko Kawaguchi (APAC)

Session 4: Managing and Conducting the Review

Ms. Shu-Ping Huang (TFDA)

Session 5:Bringing Consistency and Efficacy to Regulatory Decision-Making

Dr. Lawrence Liberti (Temple University

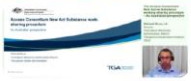
Session 6: Communication

Dr. Shinji-Hatakeyama (APAC)/ Ms. Yu-Ju Lin (CDE)

Workshop Program (3/5)

Topic of Special Interest I: Promoting Regulatory Cooperation

Session 7: The ACCESS Consortium New Active Substance Work-sharing Procedure- An Australian Perspective



- Overview of TGA's reliance pathways and principle-where does ACCESS fit and what is ACESS?
- Key features of the work-sharing process
- Dr. Michael Shum (TGA)

Topic of Special Interest II: The Application of RWD/RWE in Regulatory Decision Making

Session 8: Considerations of the Application of RWD/RWE in Regulatory Decision-Making

- Introduction, examples and regulatory perspectives of RWD/RWE
- Dr. Chi-Hsun Chen (CDE)

Workshop Program (4/5)

PART 2: Live Videoconference (Sep 14-16)

Day 1: Sep 14

Group Discussion

Case Study:
Planning of Submission and Preparation of Application Dossier (New Drug/Generic Drug)

Presentation and Sharing by Economic Representatives

Case Study:
Managing and Conducting the Review
- Fixed Dose Combination Products

Day 2: Sep 15

Workshop Program (5/5)

Day 3: Sep 16

Topic 1

Regulatory Measures in Response to COVID-19 in Chinese Taipei

Speaker: Dr. Shou-Mei Wu Director-General of TFDA

Topic 2

International Collaboration in Time of COVID-19: The Need for Regulatory Agility

Speaker: Dr. Agnès Saint-Raymond of EMA

Topic 3

Regulatory Challenges Against COVID-19 Experiences Sharing of Japan

Speaker: Ms. Yuriko Takemura of PMDA

Topic 4

Expectations from the Workshop

Speakers: Mr. Daisuke Koga (PMDA)
Dr. Shinji Hatakeyama (APAC)
Dr. Ping-Chiang Lyu (RAPS TW)

Feedbacks-General Satisfaction

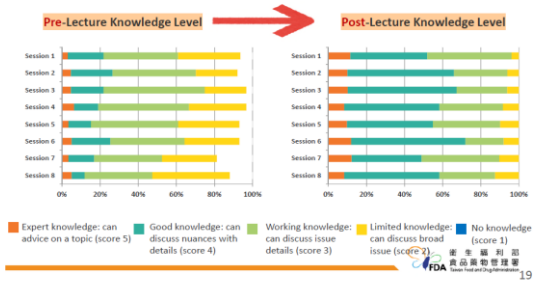
Scale 1=poor and 5 =excellent

General Satisfactions	Average Satisfaction
Did the workshop strengthen your understanding of GRM concept?	4.2
Did the workshop meet your expectations?	4.1
Overall Seminar Quality (Well-organized).	4.3

With the average score above 4, the 2021 APEC GRM CoE could be considered as satisfying to the participants.

Knowledge Level of Each Session

The knowledge level of the workshop increases in every session.



Summary of Feedbacks

GOOD!

Most sessions received very good satisfaction and feedbacks!

- Well arranged and very informative workshop with great topics.
- The workshop is already very good with training methods, focus group discussion, problem solving and discussion with the expert.
- Really loved the constant reminders from facilitators and appreciate the pre-assignment of roles.

(To name just a few)

Most useful topics of this year's GRM CoE Workshop:

- Regulatory challenges against COVID-19
- Case studies and discussions
- Planning of Submission
- Bridging consistency in regulatory decision-making
- Work sharing

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Workshop Photos (1/2)

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Workshop Photos (2/2)

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Future Plans

FUTURE PLANS

YEAR 2021

- Host 1 APEC GRM CoE Workshop either virtually or face-to-face (depend on the COVID-19 pandemic) in the second half of year 2022.
- Host 1 local GRM Training in the second half of year 2022.

TFDA will host 1 domestic GRM trainings in November 2021

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附件 5、APEC RHSC 線上會議會議紀錄(由 RHSC 秘書處提供)

Dear RHSC Members and Affiliates,

We greatly appreciate all of those who were able to participate in the virtual RHSC meeting this week. In spite of some challenging conditions, we are appreciative of the work that has continued and the enormous progress that we continue to make in promoting regulatory convergence in the region and beyond. We would like to share the meeting outcomes with you, and would appreciate your noting any deadlines that pertain to your party:

All PWA Champions are encouraged to revise their roadmap using the new simplified template, including a review and updating of the training objectives, Core Curriculum, and library of internationally-recognized standards upon which the core curriculum is based. Most importantly, each PWA should develop several concrete, measurable KPIs to express our progress at transparent manner. The AHC will use them in collating and publishing our progress towards regulatory convergence. (Please see attached new roadmap template). PWA Champions are asked to submit the revised roadmap to the Secretariat in early-mid January 2022, for circulation to the RHSC and discussion at our next SOM-1 meeting in 2022 (Feb 2022 timeframe).

PWA Champions are reminded to host a PWA Steering Committee meeting at least twice per year to keep documents updated and to share information across CoEs.

There are several CoEs whose 5year term is expiring in 2022. (Please see attached chart.) Affected PWA Champions should use the CoE Assessment Tool as a guide in reviewing the past performance of any CoE that wishes to renew their status. The PWA Champion(s) should contact the CoE Director to ask if the CoE wishes to renew for another 5-year term.

If yes, please follow the procedure outlined in the attached CoE Assessment Tool. We suggest completing the process 1-2 months before the CoE expiration date.

Minor updates to the CoE Operating Model will be circulated in early 2022 for review and endorsement by the RHSC.

Based upon the information we heard from the PWAs, our Secretariat Serene has updated the 2021 CoE Workshop chart (attached), and created a new chart for 2022. Please review and alert Serene to any needed revisions.

With regards to the Rare Disease Network presentation, please send any ideas you might have on collaborations to the Co-Chairs and Serene for further consideration.

Attachments:
New Roadmap Template
CoE MOU 2022 expiration chart
CoE Assessment Tool
CoE Operating Model
2021 CoE workshop chart
2022 CoE workshop chart

With kind regards to all,

Dr Michelle Limoli and Dr Nobumasa Nakashima
RHSC Co-Chairs