出國報告（出國類別：出席國際會議）

赴印尼參加亞太經濟合作會議醫療利害關係者意識高階研討會：型塑醫療器材和生物製藥行業的道德環境

APEC Healthcare Stakeholders Awareness High-Level Workshop: Fostering Ethical Environments in the Medical Device and Biopharmaceutical Sectors

服務機關：法務部、法務部廉政署

姓名職稱：朱坤茂 署長、范宜愷 廉政官、

張漢書 科員

派赴國家：印尼・巴里島

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壹、會議行程紀要

一、會議時間：2013 年 9 月 2 日

二、會議地點：印尼巴里島

三、會議主辦國：美國

四、會議進行情形：

本次會議由美國主辦，邀請來自美國、澳大利亞、汶萊、加拿大、智利、中國大陸、中國香港、印尼、日本、馬來西亞、墨西哥、秘魯、菲律賓、新加坡、泰國、越南及我國等 17 個會員體中之醫生和醫院協會、醫療監管者及反貪腐官員等，共約 77 名代表出席與會（議程如附件 1；與會名單如附件 2）。

（一）開場介紹

本日會議首先由印尼巴里島巴東區攝政 A. A. Gde Agung 與印尼中小企業合作部部長 H.E. Syarifuddin Hasan 進行開幕致詞，歡迎各經濟體參與本次會議，為提升發展當地更好的醫療器材和生物製藥產業而共同努力。

接著由主辦國計畫主持人 Ms. Lynn Costa（美國商務部中小企業商業倫理倡議計畫監督者及貿易發展資深顧問）引言，表示本 APEC 跨年度計畫自 2010 年開始至今，獲得 APEC 經費之補助，非常感謝各經濟體的參與，鑒於私人企業中有 90％為中小企業（SME）規模，醫療領域中則有 70％為中小企業，另外生技製藥與建築工程亦是兩個非常重要的領域，需要利害關係者（stakeholders）共同協力推動。再者，前一週才在馬來西亞吉隆坡舉辦種子人員培訓，共計 125 位代表參訓，非常感謝馬來西亞反貪污委員會（MACC）之支持與配合。

另由 APEC 中小企業工作小組（SMEWG）主席 Dr. Wimonkan Kosumas（泰國中小企業促進署副署長）致詞，介紹 APEC 於醫療器材及生技製藥領域有關商業倫理之領導地位，本計畫之啟動來自於 2010 年中小企業工作小組之部長會議，由美國主辦，並相繼於 2011 年制定「吉隆坡自願性倫理準則（下稱吉隆坡原則）」

（The Kuala Lumpur Principles-Medical Device Sector Codes of Ethics）、「墨西哥市自願性倫理準則（下稱墨西哥市原則）」（The Mexico City Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector），2012 年於中華臺北針對生技製藥產業自願性規範進行後續之討論，本次會議目的在產生「努沙杜瓦承諾」（Nusa Dua Statement）。

（二）第一場議程

第一場議程為上午 9 時 00 分至 10 時 00 分，主題為「APEC 迄今於提升倫理標準與成果之領導地位」（APEC Leadership in Heightening Ethical Standards & Results Achieved Thus Far），主席為 Ms. Lynn Costa（美國商務部中小企業商業倫理倡議計畫監督者及貿易發展資深顧問），分別由馬來西亞、墨西哥、美國與加拿大等 4 位代表發表 10 分鐘演講後，進行 20 分鐘與談。

本場次對下列議題提供概述：為何 APEC 要推動「APEC 中小企業商業倫理」倡議？為何此倡議要包含來自政府部門、產業界、學術界/公民社會之專家？迄今為止之成果（針對相關產業制定之自願性規範，如：吉隆坡原則與墨西哥市原則）；維持與型塑醫療照護領域的倫理環境之挑戰與機會。茲將各講者演講重點摘陳如次：

1、 馬來西亞中小企業公司執行長 Dato’ Hafsah Hashim（吉隆坡原則起草專家工作小組之聯合主席）

Dato’ Hafsah Hashim 報告分享起草「吉隆坡原則」之動機及原由，制定自願性規範之原因在於企業之不道德行為，在經濟層面傷害國家經濟，在商業層面傷害廠商，故先選定這些與安全有關之領域（如：醫療器材及生技製藥領域與醫療照護安全有關，建築工程則與公共建設安全有關）制定自願性規範。

2、 墨西哥經濟部國際關係處處長 Mr. Ivan Ornelas Diaz（墨西哥市原則起草專

家工作小組之聯合主席）

Mr. Ivan Ornelas Diaz 報告分享起草「墨西哥市原則」之動機及原由，墨西哥市原則與前述吉隆坡原則均於2012年俄羅斯主辦之APEC會議中被採認。

3、 美國先進醫療協會（AdvaMed）副總裁及法律長 Mr. Chris White（吉隆坡原則起草專家工作小組之聯合主席）

Mr. Chris White 提及吉隆坡種子人員培訓之目標在建立普遍及廣泛的共識，建立特定行動計畫，及形成 APEC 最大之網絡；並表示各會員體在建立醫商間道德規範上，因其現有經濟環境的不同而有差異性，故各國政府仍需先考量國情後再予個別制定其倫理守則或規範。

4、 加拿大 Rx&D 公司總裁 Mr. Russell Williams（墨西哥市原則起草專家工作小組之聯合主席）

吉隆坡原則及墨西哥市原則僅揭示了原則性規範，尚需進一步制定讓醫事人員及相關廠商能自願遵守之守則，建立起共識及相關的培訓計畫後，重點是如何共同合作以面對挑戰。

（三）第二場議程

第二場議程時間為上午 10 時 15 分至 11 時 30 分，主題為「確保醫療照護領域之高道德標準：醫院、醫生及產業合作之重要性」（Ensuring a High Standard of Ethics in the Healthcare Sector: The Importance of Hospitals, Physicians, and Industry Collaboration），主席為美國先進醫療協會（AdvaMed）副總裁及法律長 Mr. Chris White（吉隆坡原則起草專家工作小組之聯合主席），分別由秘魯、澳大利亞、香港、中國大陸及日本等 5 位代表發表 3 至 10 分鐘演講後，進行 45 分鐘與談。茲將重點臚陳如次：

1、 秘魯 Lima 商會副主席 Mr. Mario Mongilardi Fuchs

Mr. Mario Mongilardi Fuchs 表示建立醫商間高標準的道德規範，需要公部

門、醫療院所及相關廠商等各界的合作，且需要長期的努力。

2、 澳大利亞骨科協會（AOA）專業發展與標準部主任 Dr. Andreas Loefler（附件 3）

Dr. Andreas Loefler 表示協會之共同目標在於推動革新、提供病患安全及保持信任，而企業、醫生及政府有其各自不同的特定目標，如：企業需要利潤及臨床結果、醫生需要病患與收入、政府需要提供衛生保障及規範企業等。在企業方面，需要新產品、安全及銷售員，其中安全部分需要臨床前的試驗、臨床實驗與報告，並以醫生為目標；在醫師方面，需要有完整的訓練、善待病患、享受社區對他的信賴，並相信新的科技；其中的誘因在於特許權與諮詢費、教育支援、海外旅行，甚至美食美酒及橄欖球賽的門票等。在這裡包含三方角色之不尋常的企業模式：企業經營商品、醫師選擇商品、政府購買商品。

Dr. Andreas Loefler 另提及面臨之倫理問題為：未測試藥物或器材、希望事前告知、檯面下交易、高成本的新產品、缺乏科學證據與使用證書之過度廣告等。應以更好的方法解決：不直接付費給醫師、隨機控制、至少追蹤 2 年、獨立評鑑、同儕評論的出版品、註冊制度（如：AOA 國際聯合註冊制度）；另介紹澳大利亞現有之倫理規範，如：澳大利亞整形外科協會、皇家外科學院、醫藥協會、醫療科技協會等均有倫理規範。在與企業的互動上，AOA 行動宣言包含：遵照病患意願、避免商業性說服、公開財務狀況、拒絕餽贈、通知贊助廠商等。AOA 並參考澳大利亞醫療科技協會（MTAA）之規程有關企業可做與不可做之事，及如何與醫師互動。至於立法方面，使用推薦廣告及製造非現實之預期係違背醫藥規範之行為，公司負責人應誠實行動，並處罰對公務員行賄之行為；另外，政府應遊說企業及病人遵循倫理規範。

3、 香港製藥業協會執行董事 Ms. Sabrina Chan

香港代表 Ms. Sabrina Chan 表示在醫商間建立高標準的道德規範，在實際的執行上確有困難，因為追求透明對於具有獨立且高社會地位的醫師而言衝擊太大；醫療廠商應明確瞭解何種行為被規範；在醫商互動關係未能完全透明前，需不斷地修正相關的道德規範及討論溝通，然而，此舉相對地也可能會陸續揭露出醫商間的不當關係。

4、 中國醫院協會副總裁兼秘書長 Mr. Li Hongshan

Mr. Li Hongshan 表示中國醫商互動的狀況與其他國家情況並無太大差異，其政府將持續致力於反制相關行賄者，以改變醫療行業之傳統習慣；2014 年 APEC 將於中國主辦，其在此表示歡迎之意。

5、 日本醫學協會執行董事會成員 Dr. Masami Ishii

Dr. Masami Ishii 表示就亞洲國家既存的醫商文化而言，在醫商間建立高標準的道德規範確有其困難，醫療照護之革新需要透過相關人員的溝通來共同達成。

（四）第三場議程

第三場議程時間為上午 11 時 30 分至 12 時 30 分，主題為「瞭解政府在創造醫療照護輪理環境之角色：亞太地區經驗分享」（Understanding the Role of Governments in Creating an Ethical Healthcare Environment: Learnings from Across the APEC Region），主席為馬來西亞中小企業公司執行長 Dato' Hafsah Hashim（吉隆坡原則起草專家工作小組之聯合主席），分別由馬來西亞、菲律賓、印尼、泰國、我國及新加坡等 6 位代表發表 3 至 10 分鐘演講後，進行 15 分鐘與談。茲將重點臚陳如次：

1、 馬來西亞反貪污委員會副委員長 Dato ‘ Sutinah binti Sutan（附件 4）

Dato ‘ Sutinah binti Sutan 首先介紹馬來西亞政府於醫療照護領域反貪腐策

略中所扮演之角色，其中政府應致力於解決或減少貪腐、清除貪腐根源及利於其擴散之條件，並應建立良好之道德環境。另分享該國有效落實反貪腐策略之經驗，主要因為其強而有力之法律，如：馬來西亞反貪污委員會法、刑法、選舉違反法、反洗錢及恐怖份子融資法、刑事事項互助法、揭弊者保護法及證人保護法等。此外，尚有企業誠信承諾，由企業自願宣布不會有貪腐行為、將努力營造免於貪腐之商業環境，及遵守企業反貪腐原則等。

前述反貪腐原則包含：（1）承諾（Committing）—促進良善公司治理、透明、課責與誠信價值。（2）強化（Strengthening）—支持防貪的內部機制。（3）遵循（Complying）—有關打擊貪腐之法律、政策及流程。（4）打擊（Fighting）—任何形式的貪腐行為。（5）支持（Supporting）—馬來西亞政府及反貪污委員會之防貪倡議。

Dato ‘ Sutinah binti Sutan 另提及財政部 2010 年發布之誠信條約（Integrity Pact），係校長或計畫主持人及所有投標者間之公共／私人契約之協議，承諾屏除賄賂、共謀及其他貪腐行為，透過監控系統達到課責、透明。另該國企業反貪腐政策與指引，規範收受禮物、政治獻金、慈善獻金／贊助、疏通費、招待／娛樂費、利益衝突、轉診政策及企業社會責任等；至於其他預防工具則為：於招標文件列入反貪腐條款、財政部對於違反採購規定之公司發布處罰通函（如：撤回投標、列入黑名單等）、政府指引支持信、獎勵公務員舉報貪腐之政府通知、申請政府補助或貸款時要求有商業倫理守則。最後，尚需要監控制度定期評估，及辦理相關訓練與教育課程，並擴及於有夥伴關係之相關協會及監管機關。

2、 菲律賓衛生部食品藥物管理局代理局長 Dr. Kenneth Hartigan-Go（附件 5）

Dr. Kenneth Hartigan-Go 提出一個公式 C = M + D - A（貪腐=獨占+處理權-課責），無論在公部門、 私部門或非利益團體，此公式在解釋「貪腐」的成

分上都能夠適用。世界銀行估計每年約 5%的全球 GDP 損失來自於貪腐，另一個報告也指出每年光是用於行賄的金額即達 1 兆美元，這還不包括其他形式的貪腐。在世界各國，政府的功能是保障社會穩定，為達成此目標，政府需要人民的信賴，因此「信譽」是必須被保護的重要社會資產。政府必須依法行政，一系列的法律規範被制訂，而違背法律將導致社會的不和諧；而在法律之上，還有道德。至於如何將道德原則落實為具體規範，因為道德是個人內在的價值，無法被公諸於眾並評價，但或許由道德衍生的具體行為，則是可以用來監測及衡量的。

關於內在約束或外部控制，何者較有效？經驗而論，光靠個人內在的約束，在醫療專業團體中並不總是有效的，但過於嚴格的外部控制也容易導致醫療改革，並在企業及醫院間產生不道德的業務行為。一個可能的解決方式是將政府所有單位視為一體，發生倫理問題的部門無法被隔離，因為它會影響其他政府機關，但政府如何為自己訂定高道德標準？現階段仍存在困難。另一種選擇是將整個社會視為一體，由社會大眾扮演監督者，令政府或私部門違背倫理的行為不會被掩蓋。

Dr. Kenneth Hartigan-Go 提及菲律賓之社會文化現象使其在道德困境中難以做出選擇，如：對借款表示感謝、字面上感到羞恥、共同之歷史連結、後台強硬之比較；上述現象更常出現於管理階層，儘管他們表面上宣稱透明。另表示 APEC 倫理準則不只涵蓋企業，也包括醫療專業機構和政府，因此有必要在醫療部門規劃高標準的藍圖，作為標竿學習之用。現階段在醫療部門，許多違背倫理的行為都是約定俗成的，而老一輩的作法會成為新進人員之榜樣，追根究底，這些行為源自於醫療單位或政府人員覺得他們的收入不足。此外，企業界、媒體、社會及大眾有時會將政府官員冠以「特權」之名，而導致一連串的不幸事件，如：將本應是公僕的政府官員視為某種名流，並預

設其擁有某些利益；藉由審計的幻覺，認為高層官員亦同流合污；最後產生逆向斯德哥爾摩症候群以保持現狀及既得利益。領導者常常忘記，當他們離開辦公室或卸下權力後，沒人會再記得他們。最後，Dr. Kenneth Hartigan-Go 表示良善治理是強化醫療體系的六大架構之一，它擁護透明及課責之政策，因此必須將倫理層面整合進決策及行動中。

3、 印尼衛生部衛生技術和全球化衛生部長的資深顧問 Professor Agus Purwadianto（附件 6）

Prof. Agus Purwadianto 首先簡單介紹吉隆坡原則與墨西哥市原則之特色與重疊之處。醫療器材部分，比較吉隆坡原則與印尼醫療器材與實驗室協會倫理行為規範（Code of conduct of Association of Medical Devices and Laboratory Indonesia）之不同，前者聚焦於與醫療人員互動之倫理指引（如：醫生），Gakeslab Code of Conduct 則集中於遵守現行政府法規倫理貿易政策，若吉隆坡原則被採納，會出現潛在問題，如：處理招待與商業倫理之模糊地帶，因為這些細節並未出現在 Gakeslab Code of Conduct。吉隆坡原則只是指引，每個國家都有採用內容之自由。

生技製藥部分，印尼以良好藥品監管實踐（Good Drug Regulatory Practices ，GDRP）確保安全性、有效性及藥品質量，GDRP 包含：以科學基礎期前控制市場之能力、期後市場控制之一致性與準確性、以高嚇阻作用執法。另，尚有製藥產業倫理行為之監測系統，如：藥品行銷訊息之控制，確保訊息之完整、客觀及不誤導；且製造商與營銷單位須依商業倫理規範與醫療協會、醫院協會及醫師協會互動。Prof. Agus Purwadianto 提及印尼醫療協會倫理規範（KODEKI），其中第 3 條包含墨西哥市原則之解釋，KODEKI 於 2012 年 12 月在 Makassar 印尼醫師協會合法化，普及於 245 個分會、33 個會議倫理專家及 17 個協會，且自 2004 年，印尼醫師協會與印尼製藥協會已同意設

立聯合小組，以追訴雙方違反行為規範者。

至於政府在強化倫理環境所扮演之角色，印尼製藥商協會、醫療協會、醫院協會及藥師協會等，均應遵守全國性醫療產業之倫理行為（National Board on Ethical Conduct in Health Industries），應定期舉辦研討會、人力資源訓練、監測與評估。

4、 泰國醫學委員會主席 Dr. Somsak Lolekha（附件 7）

Dr. Somsak Lolekha 表示泰國在 2000 年時已經有關於醫生與醫療照護產業之間的道德規範，它包含了 6 章，並介紹第 41 條至第 46 條之規定，包含醫生不應接受醫療照護產業之任何金錢，除非是顧問費、學術講座酬金、研究酬金；醫生不應接受任何禮物、服務或超過 3,000 泰珠之娛樂價值，除非是學術貢獻之項目，且有利於病人服務，可以其機構之名義接受；當接受企業贊助國內或國外之考察訪問、參加會議或學術講座時，醫生僅可接受自己的旅費、註冊費、講座酬金、餐點及住宿費，且限於考察訪問、會議及講座之期間等。並規定若醫生未遵循規定，及有人投訴醫學委員會的話，他將會被調查。懲罰包含警告、譴責、暫停執照或吊銷執照。

Dr. Somsak Lolekha 認為墨西哥市原則是可以被接受的，且與泰國藥品研究與製造商協會 2008 年公布的第 8 版的銷售與行銷實務規範（PReMA）相似。為控制貪腐與倫理，必須強化供需雙方，而隸屬於泰國政府的製藥組織從未遵循上述規範。泰國政府的製藥組織不是好模範，造成當地販賣通用藥物的製藥公司也不遵守銷售與行銷運作實務規範，因為它是自願性規範而無強制性，它應該由政府定為法律或規定。在泰國醫生的回扣是不道德的，但有些製藥或醫療器材公司選擇支持有很多病人的醫生。當公司藉由捐助金錢給機構或組織以挑選適合的醫生參加海外會議，被選出者往往不是該領域的人，他們挑選對該公約主題一無所知的署長或高階官員參加會議，而在此主題辛

苦耕耘的醫生卻未雀屏中選。

至於是否該追隨法國及美國的陽光法案，或醫生財務透明報告？Dr. Somsak Lolekha 認為應該等待，並視該方案有利及不利之影響。透明是好事，但必須有限制且不侵犯隱私與秘密，當通過安全檢查，就不需赤裸裸地展現透明。因此可用其他方式檢查，使所有醫生向國稅局申報其收入及收入來源，但不需要將其收入公開在網站；政客、媒體、故員及非政府組織則需要將其收入來源公布在網站。

5、 我國法務部廉政署署長朱坤茂（附件 8）

我國代表法務部廉政署署長朱坤茂提出有關「中華臺北醫療利害關係者聯合行動」之報告，首先針對 Ms. Lynn Costa 於醫療器材、生物製藥及營建業領欲，推動各經濟體訂立各自之 APEC 倫理規範乙事表示欽佩與推崇。再者，我國監察院和立法委員鑒於近年來發生醫材廠商涉嫌行賄醫療管理高層及醫院醫師，勾結圍標醫院採購弊案，暴露出醫療體系長期以來的問題，均要求衛生福利部應針對公立醫院之醫師與廠商間之分際，檢討訂定更明確之倫理規範。

目前我國公私部門醫商互動倫理之規範有：1999 年醫師公會通過「醫師倫理規範」、2006 年衛生福利部公告「醫師與廠商間關係守則」、2008 年行政院通過「公務員廉政倫理規範」及中華民國開發性製藥協會（IRPMA）2010 年發布「市場行銷施行標準」。然而，為訂定統一的醫事倫理規範，由衛生福利部於 2013 年 2 月 7 日召開「研訂醫商倫理守則平臺」會議，決議研訂醫療專業人員與醫療器材及生技製藥廠商共同適用的倫理守則具可行性及必要性，且訂定於同一規範中，不再分別訂立適用標準，僅針對二產業不同利益衝突態樣另立專章加以規範。

最後，朱署長表示法務部廉政署是我國的廉政專責機關，會積極參與醫事倫

理規範之制訂，並希望不僅是訂立一個宣示性的規範，而是更實際地提供各利害關係者共同適用與遵循的標準。

6、 新加坡衛生科學局保健產品監管組期前市場部代理助理組長 Ms. Lee Hui Keng

Ms. Lee Hui Keng 表示欲將此二產業之倫理規範結合，需要政府推動研究。

（五）同步分組討論

本場次議程時間為下午 1 時 30 分至 3 時，分別就醫療器材與生物製藥等二面向分為 2 組，針對如何啟動當地行動計畫以提高醫療照護利害關係者之倫理互動，並支持依 APEC 原則訂出之有效產業倫理規範之議題同步進行分組討論。

1、 醫療器材產業小組討論之歸納重點如下：

（1）應於醫、商間維持良好溝通關係

公部門應蒐納私部門（企業及利害關係者）之回饋意見；醫、商間如有合作關係應予透明，且應將其「透明度」作清楚之定義；應強化醫事倫理及道德規範之相關教育，提升公眾意識，進而承諾遵守及踐行；需要秉持堅定及積極之態度予以貫徹執行。另泰國代表分享該國線上競標機制；澳洲代表則分享該國公司法之相關規範。

（2）各會員體應採取共同之具體行動

有關醫商間之合作關係應對外公開、宣布；在教育方面應建立經驗交流分享及共同合作關係；妥善運用媒體影響力（如：對相關規範之說明運用，醫商間良好互動的道德規範等），予以宣導並建立共識；需要定期檢視並公開其推動相關措施之進展及更新情形；對於醫療器材採購應建立完善的電子採購制度。

2、 生技製藥產業小組討論之歸納重點如下：

（1）推動方向

各與會經濟體代表一致認為「宣導」方式之效果將遠大於「查處」，畢竟此類倫理規範或自願性規範並不具備強制力，政府亦無權要求企業遵守該規範或對違反規範之企業施予裁罰，是故，如何透過各種宣導方式令企業「自願地」訂定相關倫理規範並遵守，即成為本次討論之重點。

（2）推動策略

透過各式管道廣為宣導「墨西哥市原則」之概念與精神；塑造企業倫理環境的氛圍，以增加企業涉入程度；與其他國際組織建立夥伴關係，如國際製藥聯盟（IFPMA）；根據墨西哥市原則之精神，再訂定更具體的實踐守則；由政府方面提供誘因（如：企業倫理認證），使企業更願意加入本計畫；發布年度研究報告，將符合倫理規範之優良企業名單公諸於社會大眾；於各企業訓練種子教官，使其扮演企業內倫理規範之推手；以長期面而言，仍應將倫理概念落實於教育當中。

3、 小結（附件 9）

對醫療專業機構（醫師、護理師、藥劑師）部分，建議將企業誠信列入醫事學校及訓練計畫之課程，鼓勵採用 APEC 吉隆坡原則及墨西哥市原則，另建議在每一個醫療專業機構選拔廉潔楷等。對 APEC 會員國政府部分，除鼓勵採用 APEC 吉隆坡原則及墨西哥市原則外，確保所有相關政府機構之參與，並在每個相關機構選出強化企業與醫療機構間誠信互動之模範人員等。對企業部分，則鼓勵各企業發展並落實與吉隆坡原則及墨西哥市原則一致之倫理準則，支持在企業學院、公務人員學院、醫事學院及醫療專業機構中實施企業誠信課程等。對 APEC 部分，建議持續在所有利害關係者間推動公開對話，發展透明與揭露之議題，分享各國經驗（如：誘因、規範制度、強化機制、訓練計畫），定期進度報告，將吉隆坡種子教官訓練對象擴充至醫師及公務人員（原只限定在企業界），與相關組織合作（如：國際藥品制造商協

會聯合會 IFPMA 或其他擁有可供 APEC 借鏡工具之組織）等。

（六）努沙杜瓦宣言（Nusa Dua Statement）

本場次進行時間為下午 3 時 30 分至 4 時 30 分，由加拿大 Rx&D 公司總裁 Mr. Russell Williams（墨西哥市原則起草專家工作小組之聯合主席）及馬來西亞中小企業公司執行長 Dato’ Hafsah Hashim（吉隆坡原則起草專家工作小組之聯合主席）擔任主席，會中各與會國對型塑醫療照護領域倫理環境之努沙杜瓦宣言共同討論，此宣言將提交 APEC 中小企業工作小組及部長會議。重點摘述如下：（附件 10）

1、 為了在 21 個 APEC 會員經濟體中建立共識，以型塑醫療器材和生物製藥行業的道德環境，來自 APEC 區域中的醫療專業組織、反貪腐機構、衛生部門、衛生規範機構、政府採購部門、生物製藥及醫療器材協會、私部門醫療業界，在印尼政府衛生部門、中小企業部門及「APEC 中小企業誠信倡議」的聯合邀請下，於 2013 年 9 月 3 日在印尼努沙杜瓦相聚。

2、 產業界、醫療界及政府部門的合作能夠改善病患的生命安全，並獲致高效能及高品質的醫學科技療法。此外，上述合作是有必要的，如此方能革新醫學科技療法以迎合病患需求，將持續透過對話，使醫療產業與企業倫理緊密結合。

3、 重申 2012 年 APEC 領袖會議對貪腐的陳述：「是對 APEC 會員經濟成長、人民安全以及投資合作的巨大障礙」，以及「我們認為企業及公私部門夥伴關係在促成企業倫理及結合政府、企業、利益團體共同打擊貪腐的努力中扮演了重要角色。」

4、 重申對「醫療器材產業建立自願性規範之吉隆坡原則」及「生物製藥產業建立自願性規範之墨西哥市原則」的支持。我們承認 APEC 中小企業工作小組在推動企業、政府及公民社會發展高標準行為規範的領導地位。

5、 同意吉隆坡原則及墨西哥市原則（合稱 APEC 原則）在推動醫療業界的經濟成長上，踏出了重要的第一步。另同意作為醫療專業組織、衛生規範機構、反貪腐機構、政府採購部門、醫療業界的領導，我們有責任在 APEC 會員經濟體中共同塑造醫療行業的道德環境。這項工作是 APEC 促進經濟合作核心任務之基礎，因為健康的人口是經濟永續成長的基本條件，而且隨著經濟體的發展，對人民健康的需求及標準也會提高。

6、 因此針對每一種利害關係者建立獨特且重要的角色，以促進醫療行業的道德環境。醫療產業應該遵循高道德標準，如：APEC 原則，及所有相關法律規範，並在此條件下發展對病患有益之衛生技術及醫療方法。醫療專業機構有責任為病患考量，並理解他們扮演著居中聯繫協調的角色，幫助各利害關係者建立道德標準，如：APEC 原則。衛生部門及醫療規範機構應瞭解企業倫理規範之價值，並推動所有利害關係者支持這些規範，如：APEC 原則及其他全國性或地區性倫理準則。政府及私部門採購單位在採購醫療產品及服務時，應秉持透明、道德、乾淨原則，及可課責的政策、程序與過程。反貪腐機構應該建立清楚的法律，並鼓勵企業建立自我規範，以符合 APEC 原則及其他全國性或地區性倫理準則之要求。

7、 我們同意持續地能力建構、對話及高層的支持，是推動這項工作的關鍵因素。因此呼籲 APEC 將「APEC 中小企業誠信倡議」制度化，並建立高階「APEC 企業誠信論壇」，透過能力建構、經驗分享、利害關係者間對話等方式促進區域合作及強化企業誠信之實踐。此論壇將同時塑造外在企業環境及內部公司環境之倫理，建立永續基礎。誠信合作也能夠促進病患生命安全，強化醫藥科技及療法，並支持醫學創新之發展。

（七）會議結束

本日會議於下午 5 時結束，由 Ms. Lynn Costa 主持閉幕式，表示本次會議係為

了維持產業及政府間的良好溝通及聯繫，並共同致力於促進相關資訊之公開及透明，各會員體將採取個別行動（individual actions），健全公私醫療部門人員與兩產業間之良性連結，另各會員體亦將採取共同行動（collective actions），除了推動相關法規外，應強化道德倫理及群眾意識（public awareness）之教育。最後，期盼藉由 APEC 平台促進兩產業道德倫理相關議題及政策措施之交流，分享目前推動之最佳範例，作為各會員體未來制定相關政策之參考，並宣布本次會議結束。

貳、心得與建議

一、本次大會出席代表對於營造及型塑公私部門醫事專業人員與相關廠商（如:醫療器材和生物製藥等）良性互動之道德環境皆有共識，自 APEC 訂定吉隆坡原則與墨西哥市原則後，期待各經濟體將之推廣於各自國內之產業，並由各產業甚至企業訂定自身之倫理規範，此課題不但備受重視，且為國際潮流之趨勢。

二、現今關於醫療器材與生物製藥等研發製造乃日新月異，醫、商界間的溝通互動乃是不可或缺及勢在必行；惟鑑於以往我國健保制度曾遭受藥價黑洞的威脅，及日前爆發公立醫院高層醫師收受醫材廠商賄絡之醜聞，故如何將醫商間關係導向良性連結，而非不當勾結以致妨害民眾權益及國家利益，是值得我國持續關切及努力貫徹的課題。

三、本次會議致力於推動建立各國生技製藥及醫療器材產業之倫理規範，此非政府單方面力所能及，而需由政府單位、醫療機構及企業廠商三方面共同協力，公部門部分更係跨領域地連結，包含衛生主管機關、企業主管機關及反貪腐機關等。藉由倫理規範的建立，可達到以下成效：於政府方面，促進國家的經濟成長；於醫療機構方面，提供病患優質的醫療環境；於廠商方面，塑造企業的清廉形象。有鑑於此，未來應強化公、私部門間之合作關係，積極配合上述機構之主管機關（如衛福部、經

濟部)，協力號召醫療機構及相關企業與政府結合，參考「吉隆坡原則」及「墨西哥市原則」之制定精神及原理，並審酌國內醫商界實際情勢，儘速研訂出「醫商倫理規範（或守則)」，俾供醫商界人士共同遵循，並推動企業遵守各該規範。

四、於分組討論階段中，各國代表一致認為在推動企業倫理規範的過程中，「宣導」的重要性遠大於「裁罰」。換句話說，政府機關作為協助推動企業誠信之角色，不該以查處手段嚇阻，而應透過全民參與之方式，將前述概念深植人心，並內化成為企業價值之一環，此亦與本署「廉政新構想－以民為本」概念中之「防貪先行，肅貪在後」不謀而合。綜上，建議未來妥善運用多元管道加強教育宣導公、私部門醫療人員、醫療廠商及一般民眾，以形成建立醫商間良性互動及道德環境之共識；另應進一步加強企業倫理概念之推動，其宣導對象不僅止於企業，而應定位在「全民」層次，一旦將此概念型塑成為普世價值，企業自然會為了遵守社會規範，自發性地落實企業倫理。

參、照片集錦

Sectors
APEC
APEC HEALTHCARE STAKEHOLDERS AWARENESS
HIGH-LEVEL MEETING :
Fostering Ethical Environments in the Medical Device & Biopharmaceutical Sectors
3 SEPTEMBER 2013, BALI - INDONESIA
OASIS

APEC
INDONESIA 2013
APEC HEALTHCARE STAKEHOLDERS AWARENESS
HIGH-LEVEL MEETING :
Fostering Ethical Environments in the Medical Device & Biopharmaceutical Sectors
3 SEPTEMBER 2013, BALI - INDONESIA

Ms. Fan Yi-Kai
Agency Against Corruption
Chinese Taipei
Mr. Chang Han-Shu
Agency Against Corruption
Chinese Taipei

附件 1

APEC Healthcare Stakeholders Awareness High-Level Meeting:

Fostering Ethical Environments in the Medical Device & Biopharmaceutical Sectors

Nusantara Room 3 | The Westin Nusa Dua | Bali, Indonesia | 3 September 2013

-- MEETING PROGRAM --

TIME	MEETING PROGRAM
08:00-08:30	**Registration**
08:30-08:40	**Welcome Remarks** **A. A. Gde Agung,** *Regent of Badung* **H.E. Syarifuddin Hasan,** *State Minister for Cooperatives & SMEs, Indonesia*
08:40-08:45	**Meeting Overview** **Ms. Lynn Costa**, Senior Trade Development Advisor, U.S. Department of Commerce *Project Overseer, Business Ethics for APEC SMEs Initiative*
08:45-9:00	**APEC Leadership in Business Ethics for the Medical Device and Biopharmaceutical Sectors** **Dr. Wimonkan Kosumas,** Deputy Director General, Office of SMEs Promotion, Thailand *Chair of the APEC SME Working Group*
Session One	**APEC Leadership in Heightening Ethical Standards & Results Achieved Thus Far (60 Minutes)**
09:00-10:00	**APEC Leadership in Heightening Ethical Standards** *This session will provide a brief overview of: why APEC launched the "Business Ethics for APEC SMEs" initiative; how the initiative has involved experts from government, industry, and academia/civil society; outcomes thus far (The KL Principles and The Mexico City Principles for voluntary codes of ethics for industry); and an identification of the challenges and opportunities that remain to fostering ethical environments in the healthcare sector.*

	Moderator: **Ms. Lynn Costa**, Senior Trade Development Advisor, U.S. Dept of Commerce *Project Overseer, Business Ethics for APEC SMEs Initiative* **Dato' Hafsah Hashim**, Chief Executive Officer of SME Corporation, Malaysia *Co-Chair of the Expert Working Group to Draft the Kuala Lumpur Principles* **Mr. Ivan Ornelas Diaz**, Director of International Relations, Ministry of Economy of Mexico *Co-Chair of the Expert Working Group to Draft the Mexico City Principles* **Mr. Chris White**, Executive Vice President & General Counsel, AdvaMed (United States) *Co-Chair of the Expert Working Group to Draft the Kuala Lumpur Principles* **Mr. Russell Williams**, President, Rx&D (Canada) *Co-Chair of the Expert Working Group to Draft the Mexico City Principles* *Ten Minutes Per Discussant -- Twenty Minutes for Q&A /Discussion*
10:00-10:15	**Coffee Break**
Session Two	**Ensuring a High Standard of Ethics in the Healthcare Sector:** **The Importance of Hospitals, Physicians, and Industry Collaboration (75 Minutes)**
10:15 - 11:30	**Learning from Success: Examples of Cooperation Among Hospitals/Physician Groups and Industry** **Moderator: Mr. Chris White**, Executive Vice President & General Counsel, AdvaMed *Co-Chair of the Expert Working Group to Draft the Kuala Lumpur Principles* ***Discussion Leads (10 Minute Opening Remarks):*** **Mr. Mario Mongilardi Fuchs,** Vice President, Lima Chamber of Commerce, Peru **Dr. Andreas Loefler**, Chair Professional Development and Standards and **Mr. Adrian Cosenza,** Chief Executive Officer, Australian Orthopaedic Association ***Discussants (3 Minute Opening Remarks):*** **Ms. Sabrina Chan**, Executive Director, The Hong Kong Association of the Pharmaceutical Industry (HKAPI) **Mr. Li Hongshan**, Executive Vice President & Secretary General, China Hospital Association **Dr. Masami Ishii,** Executive Board Member, Japan Medical Association *45 minutes for Q&A/Discussion*

Session Three	**Understanding the Role of Governments in Creating an Ethical Healthcare Environment: Learnings from Across the APEC Region (60 Minutes)**
11:30 – 12:30	**The Role of Government in Encouraging a High Standard of Ethics in the Healthcare Sector** **Moderator: Dato' Hafsah Hashim**, Chief Executive Officer of SME Corporation, Malaysia *Co-Chair of the Expert Working Group to Draft the Kuala Lumpur Principles* ***Discussion Leads (10 Minute Opening Remarks):*** **Dato' Hajjah Sutinah Binti Sutan**, Deputy Chief Commissioner (Prevention), Malaysian Anti-Corruption Commission (MACC) **Dr. Kenneth Hartigan-Go,** Acting Director General, Food & Drug Administration, Philippines **Professor Agus Purwadianto**, Senior Advisor, Ministry of Health, Indonesia **Dr. Somsak Lolekha**, President, Medical Council of Thailand ***Discussants (3 Minute Opening Remarks):*** **Mr. Chu Kung-Mao**, Director-General, Agency Against Corruption, Ministry of Justice, Chinese Taipei **Ms. Lee Hui Keng**, **Acting** Assistant Group Director, Pre-Marketing Division, Health Products Regulation Group, Health Sciences Authority, Singapore *15 minutes for Q&A/Discussion*
12:30 - 13:30	**Luncheon** *Location: Portraits Restaurant (located in The Westin Nusa Dua)*
13:30 - 15:00	**Concurrent Breakout Session One:** **Launching Local Action Plans for Ethical Interactions in the Biopharmaceutical Sector (90 Minutes)** **Description:** Small breakout group will discuss strategies for launching local action plans that heighten ethical interactions among healthcare stakeholders and that support the effective implementation of industry codes of ethics aligned with the APEC Principles. **Facilitated by:** **Mr. Ivan Ornelas Diaz**, Director of International Relations, Ministry of Economy of Mexico *Co-Chair of the Expert Working Group to Draft the Mexico City Principles* **Mr. Russell Williams**, President, Rx&D (Canada) *Co-Chair of the Expert Working Group to Draft the Mexico City Principles*
13:30 - 15:00	**Concurrent Breakout Session Two:** **Launching Local Action Plans for Ethical Interactions in the Medical Device Sector (90 Minutes)** **Description:** Small breakout group will discuss strategies for launching local action plans that heighten ethical interactions among healthcare stakeholders and that support the effective implementation of industry codes of ethics aligned with the APEC Principles. **Facilitated by:**

	Dato' Hafsah Hashim, Chief Executive Officer of SME Corporation, Malaysia *Co-Chair of the Expert Working Group to Draft the Kuala Lumpur Principles* **Mr. Chris White**, Executive Vice President & General Counsel, AdvaMed (United States) *Co-Chair of the Expert Working Group to Draft the Kuala Lumpur Principles*
15:00 - 15:30	**Coffee Break**
15:30 - 16:30	**Report to the APEC SME Working Group and APEC SME Ministers:** **Crafting a "Nusa Dua Statement on Fostering Ethical Environments in the Healthcare Sector" (60 Minutes)** **Facilitated by:** **Mr. Russell Williams**, President, Rx&D (Canada) *Co-Chair of the Expert Working Group to Draft the Mexico City Principles* **Dato' Hafsah Hashim**, Chief Executive Officer of SME Corporation, Malaysia *Co-Chair of the Expert Working Group to Draft the Kuala Lumpur Principles*
16:30-17:00	**Closing Remarks (30 Minutes)** **Ms. Lynn Costa,** APEC Project Overseer & Senior Trade Development Advisor, U.S. Department of Commerce
17:30 – 19:00	**Reception** *Location: Temple Garden (located in The Westin Nusa Dua)*

附件 2

APEC Healthcare Stakeholders Awareness High-Level Meeting:
Fostering Ethical Environments in the Medical Device & Biopharmaceutical Sectors

The Westin Resort Nusa Dua | Bali, Indonesia | 3 September 2013

FINAL PARTICIPANT LIST

Confirmed Participants: 63
Confirmed APEC Economies: 17

AUSTRALIA
Professor Nicholas J. Talley, President-Elect *The Royal Australasian College of Physicians (RACP)* **Dr. Andreas Loefler,** Chair Professional Development and Standards *Australian Orthopaedic Association Limited* **Mr. Adrian Cosenza,** Chief Executive Officer *Australian Orthopaedic Association Limited*
BRUNEI DARUSSALAM
Mr. Wee Shyue Liang *Pharmacist Ministry of Health*
CANADA
Mr. Russell Williams, President & Co-Chair of the Expert Working Group to Draft the Mexico City Principles *Canada's Research-Based Pharmaceutical Companies (Rx&D)*
CHILE
Ms. Macarena Guarda Maillet *General Directorate for International Economic Relations* **Ms. Claudia Valenzuela Arellano** *Women's National Service of Chile*
CHINA
Mr. Li Hongshan, Executive Vice President & Secretary General *China Hospital Association*

Mr. Joseph Cho, Managing Director
RDPAC (R&D Based Pharmaceutical Association Committee)

HONG KONG, CHINA

Ms. Sabrina Chan, Executive Director
Member of the APEC Public-Private Implementation Group, Biopharmaceutical Sector
The Hong Kong Association of the Pharmaceutical Industry (HKAPI)

Professor Fok Tai-Fai, Vice President (General Affairs)
The Hong Kong Academy of Medicine

Mr. Harry Chan, Senior Research and Trade Practices Officer
Hong Kong Consumer Council

INDONESIA

Professor Agus Purwadianto, *Senior Adviser*
MOH Technology and Globalization, Ministry of Health

Mr. Titah Sihdjati Riadhie
GAKESLAB Indonesia

Mr. Budi Praseti
GAKESLAB Indonesia

Mr. Parulian Simanjuntak, Executive Director
International Pharmaceutical Manufacturers Group (IPMG)

Ms. Endang Toekinun, Staff Regional Health
Centre International Cooperation, Ministry of Health

Ms. Sheila Kadir, Head of subdivision Regional Health 1
Centre International Cooperation, Ministry of Health

Ms. Hardini Kusumadewi, Staff Regional Health
Centre International Cooperation, Ministry of Health

Ms. Budi Dhewajani, Director of Centre International Cooperation
Ministry of Health

Mr. Doddy Izwardy, Head of Division Regional Health, Centre International Cooperation
Ministry of Health

Ms. Arianti Anay, Director of Medical Device Production and Distribution Service
Ministry of Health

Mr. Hari Nurcahyo, Country General Manager
BD (BECTON DICKINSON ASIA LTD.)

Mr. Wahid Kurniawan, Commercial Compliance Champion
BD (BECTON DICKINSON ASIA LTD.)

I Wayan Dipta, *Deputy Minister of R&D for Cooperatives and SMEs Resources*
Ministry of Cooperatives and SMEs

Martono Djohari
Ministry of Cooperatives and SMEs

Ms. Yulia Purwarini
National Agency of Drug and Food Control

JAPAN

Dr. Masami Ishii, Executive Board Member
Japan Medical Association

Mr. Yuji Noto, Manager, International Affairs Division
Japan Medical Association

Mr. Bruce Ellsworth, Director of Government Affairs
Johnson & Johnson Japan

MALAYSIA

Dato' Hafsah Hashim, CEO
SME Corp. Malaysia

Dato' Hjh. Sutinah binti Sutan, Deputy Commissioner for Prevention
Malaysian Anti-Corruption Commission (MACC)

Ms. Junipah binti Wandi, Chief Senior Assistant Commissioner
Malaysian Anti-Corruption Commission (MACC)

Miss Mayamin Haini Musa, Assistant Manager

International Cooperation Secretariat, SME Corp

Mr. Ahmad Mu'izz Mohd Yusof, Legal Advisor

SME Corp. Malaysia

Ms. Fara Zalina Mohamed, Legal Advisor

SME Corp. Malaysia

Mayamin Haini, Assistant Manager

SME Corp Malaysia

Farhana AlKhatib, Manager

SME Corp Malaysia

MEXICO

Mr. Ivan Ornelas Diaz, Director of International Relations &
Co-Chair of the Expert Working Group to Draft the Mexico City Principles
Mexican Ministry of Economy

PERU

Mr. Mario Mongilardi, Vice President
Lima Chamber of Commerce

Ms. Virginia Baffigo, President
EsSalud

PHILIPPINES

Dr. Kenneth Hartigan-Go, Acting Director General
Food & Drug Administration, Philippines

Dr. Edguardo Fernando, Chairman, Professional Regulatory Board of Medicines
Professional Regulation Commission (PRC)

SINGAPORE

Ms. Lee Hui Keng, Acting Assistant Director for the Pre-Marketing Division & Director (Covering)
for the Complementary Health Products Branch, Health Products Regulation Group
Health Sciences Authority, Singapore

Mr. Abdul Luheshi, *Vice President*
Health Care Compliance & Privacy, Janssen, Asia Pacific

CHINESE TAIPEI

Mr. Chu Kung-Mao, Director-General
Agency Against Corruption (AAC)

Ms. Fan Yi-Kai, Agent
Agency Against Corruption (AAC)

Mr. Chang Han-Shu, Officer
Agency Against Corruption (AAC)

Ms. Chen Ying-Ching, Second Secretary
Taipei Economic and Trade Office in Jakarta

Dr. Min-Huei Hsu, Counselor, Office of International Cooperation
Ministry of Health and Welfare

Mr. Lu Su-Wei, Director of Civil Service Ethics Office
Ministry of Economic Affairs

THAILAND

Dr. Wimonkan Kosumas, APEC SME Working Group Chair & Deputy Director General
Office of SMEs Promotion

Ms. Nipawis Ritthironk, Senior Operational Officer
Office of SMEs Promotion

Dr. Somsak Lolekha, President
Medical Council of Thailand

Dr. Wonchat Subhachaturas, President
Medical Association of Thailand

Pol. Col. Pokpibul Potranan, Secretary General
Office of Public Sector Anti-Corruption Commission (Ministry of Justice)

Pol. Lt. Col. Terdsak Putson, Director, Bureau of the Suppression of Corruption in Public Se
Office of Public Sector Anti-Corruption Commission (Ministry of Justice)

UNITED STATES

Ms. Lynn Costa, Project Overseer, Business Ethics for APEC SMEs Initiative
International Trade Administration, U.S. Department of Commerce

Mr. Chris White, Executive Vice President & General Counsel
The Advanced Medical Technology Association (AdvaMed)

VIETNAM

Mr. Do Minh Hung, Deputy Director-General, Drug Registration Division
Drug Administration of Vietnam (DAV), Ministry of Health

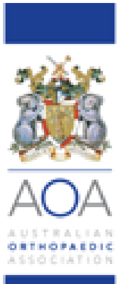
Mr. Nguyen Minh Tuan, Director-General
Department of Medical Equipment & Construction, Ministry of Health

Ms. Nguyen Phuong Lan, Deputy Director, SOE Reform Division, Agency for Enterprise Development
Ministry of Planning and Investment

BUSINESS ETHICS FOR APEC SMEs SECRETARIAT

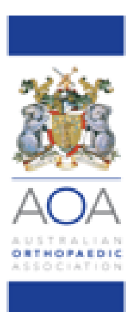
Ms. Patricia Wu

** APEC economies not represented at this meeting are: Republic of Korea, New Zealand, Papua New Guinea and Russia.*



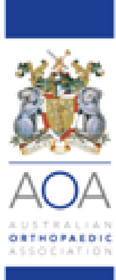
Collective Aims

- Promote innovation
  - New drugs
  - New devices
- Patient safety
  - Provide a benefit
  - Do no harm
- Keep the trust
  - of patients
  - of community



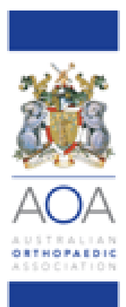
Specific Objectives

- Companies
  - Need profits
  - Answerable to shareholders
  - Need clinical outcomes
  - Need doctors to prescribe
- Doctors
  - Need patients
  - Want good outcomes
  - Want good incomes



Specific Objectives

- Governments
  - Provide health care
  - Encourage business
  - Regulate industry
    - Safety
    - Transparency
  - Control costs

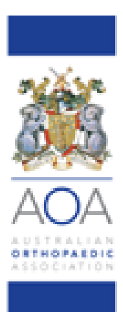


Company Perspective

- New product
- Needs safety
  - Preclinical testing
  - Regulatory approval
  - Clinical trials
  - Clinical papers
- Need sales
- Target doctors

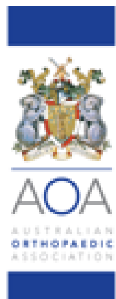
Doctors' Perspective

- Well trained and skeptical
- Treat patients
- Enjoy trust in the community
- Believes in the New (Techno Optimism)
  - Better
  - Quicker
  - Safer
  - But unproven



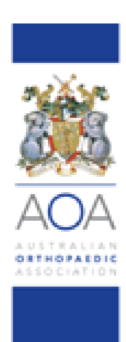
Incentives

- Direct payments
- Royalties and consultancies
- Educational support
- Overseas trips
- Wining and dining
- Tickets to rugby games



Three Parties

- Unusual business model
  - Company markets the product
  - Doctors choose the product
  - Governments pay for the product
- Educated players
  - Sophisticated industry
  - Highly trained doctors
  - Specialized government departments

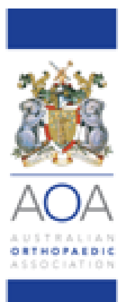


Ethical Problems

- Drugs or devices untested
- Informed consent with hope
- Payments undisclosed
- Cost of the New is usually high
- Advertisements overstated

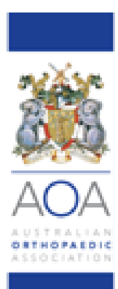
  Lack Science

  Use Testimonials



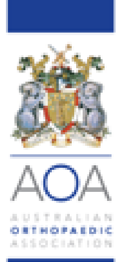
Better Way

- Company approaches institution
- No direct payments to doctors
- Randomized Controlled Trial
- Minimum 2 year follow up
- Independent assessment
- Peer reviewed publication



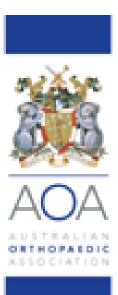
Registries

- AOA National Joint Replacement Registry
  - Captures all hip and knee replacements
  - Cooperation of surgeons, hospitals, industry
  - Government funded
  - Surgeon owned
  - Post market surveillance
  - Long term outcomes



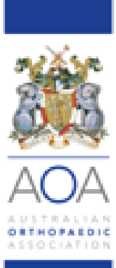
Registries

- Other registries
  - Anterior Cruciate Ligament
  - Cardiac stents
  - Breast implants, etc.



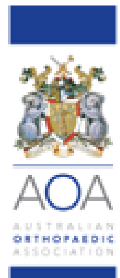
Codes of Conduct

- Australian Orthopaedic Association
  - Position Statement on Interaction with Medical Industry
- Royal Australasian College of Surgeons
- Australian Medical Association
- Medical Board of Australia
- Medical Technology Association Australia
- State and National Legislation



Interaction with Industry

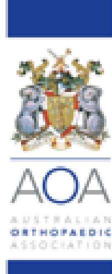
- AOA Position Statement spells out
  - To act in the patients best interest
  - To avoid commercial persuasion
  - To disclose financial interests
  - To acknowledge sponsorship
  - To refuse gifts



Interaction with Industry

- MTAA Code stipulates
  - What companies can and cannot do
  - How to interact with surgeons

- AOA requires MTAA compliance
- Regular discussion and cooperation
- Arms length funding of projects



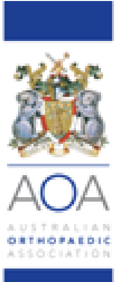
Legislation

- Illegal under Medical Board
  - To create unrealistic expectation
  - To use testimonials
- Corporations Act
  - Directors to act honestly
- Crimes Act
  - Offence to bribe a public official

  (The Brown Paper Bag)

International Code

- Global trade
  - Same pathology
  - Converging medical practice
- Companies
  - Multinationals have legal departments
  - Smaller companies need help
- Governments
  - Lobby for business
  - Lobby for patients and for ethical practice



Thank you.

APEC Healthcare Stakeholders Awareness High-Level Meeting

The Role of Government in Encouraging a High Standard of Ethics in the Healthcare Sector

Dato' Sutinah binti Sutan

Deputy Chief Commissioner

Malaysian Anti-Corruption Commission

Anti-Corruption Strategies in Healthcare Sector – the Role of the Government

GOVERNMENT

- overcome/reduce corruption
- eliminate its root causes and the conditions conducive of its proliferation
- build a sound moral environment

➢ oversight
- MOH
- MACC
  - education, training

engagement

abide by the rules

HEALTH CARE

PROFESSIONAL

➢ associations [eg: MMA, MOPI]
- by-laws
- code of ethics

INDUSTRY

➢ healthcare providers, hospitals, GP clinics
- CIP, IP

Effective Implementation of Anti-Corruption Measures – Malaysian Experience

1. Strong Laws

a. Malaysian Anti-Corruption Commission Act

b. Penal Code

c. Election Offences Act

→ criminalize acts of bribery & corruption
→ set-up an independent anti-corruption commission (ie. MACC)
→ enough powers
→ denying safe haven for corruptors

d. Anti-Money Laundering and Terrorist Financing Act

→ asset recovery

e. Mutual Assistance in Criminal Matters Act

→ technical assistance and information exchange

f. Whistleblower Protection Act

g. Witness Protection Act

3. Current Preventive Tools

THE CORPORATE INTEGRITY PLEDGE –

Voluntary unilateral declaration binding companies to uphold anti-corruption principles

- WILL NOT COMMIT CORRUPT ACTS;
- WILL WORK TOWARDS CREATING A BUSINESS ENVIRONMENT THAT IS FREE FROM CORRUPTION; AND
- WILL UPHOLD THE ANTI-CORRUPTION PRINCIPLES FOR CORPORATIONS IN MALAYSIA IN THE CONDUCT OF ITS BUSINESS AND IN ITS INTERACTIONS WITH ITS BUSINESS PARTNERS

Anti-Corruption Principles

1. **COMMITTING** to promote good corporate governance, transparency, accountability and values of integrity
2. **STRENGTHENING** internal systems that support corruption prevention
3. **COMPLYING** with laws, policies and procedures relating to fighting corruption
4. **FIGHTING** any form of corrupt practice
5. **SUPPORTING** corruption prevention initiatives by the Malaysian Government and the MACC

INTEGRITY PACT

"an agreement between the Principal or the project owner and all bidders of a public/private sector contract"

Ministry of Finance issued *Integrity Pact* directive on 1.4.2010

- tool for preventing corruption in procurement based from Transparency International model
- agreement between the government agency offering a contract and the companies bidding for it
- commitment to abstain from bribery, collusion and other corrupt practices for the extent of the contract
- accountability & transparency through monitoring system

Addressing corruption issues:
ENTERPRISE ANTI-CORRUPTION POLICIES AND GUIDELINES

- GIFT RECEIVING
- POLITICAL CONTRIBUTIONS
- CHARITABLE CONTRIBUTIONS/ SPONSORSHIP
- FACILITATION PAYMENTS
- HOSPITALITY/ENTERTAINMENT EXPENSES
- CONFLICT OF INTEREST
- REFERRAL POLICY
- CORPORATE SOCIAL RESPONSIBILITY

OTHER PREVENTIVE TOOLS AND METHODS

- **ANTI-CORRUPTION CLAUSE ON TENDER DOCUMENTS** [as an early reminder to bidders not to involve in corrupt activities while procuring tender]

- **MOF Circular Letter on Punishment for companies violating procurement rules and regulations –**
  [Withdrawal of Tender, Blacklisting, Forfeiture of Bon]

- **Government Guidelines on "Support Letters"**
  [Formal guidance to free civil servants from undue pressure from persons of influence]

- **Government Circular on Rewards for Public Officials Reporting on Corruption**

- **Requirement to have Code of Business Ethics when applying for government grants or loans.**

4. MONITORING

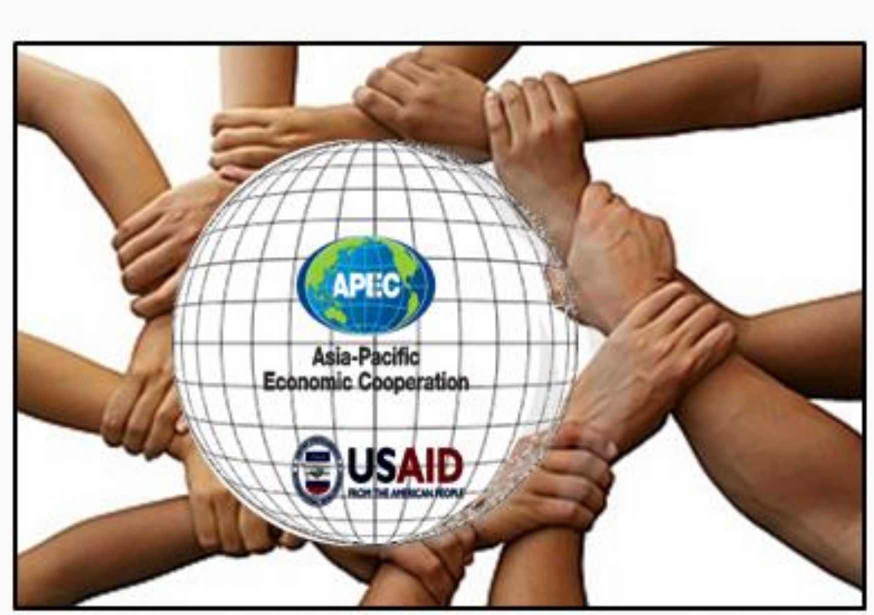
Existing Mechanism:

1. **CIP Monitoring Team headed by the MACC**
2. **Relevant Regulators**
   - **Pharmacy Enforcement Division (MoH)**
   - **National Pharmaceutical Control Bureau**
   - **Medical Device Enforcement Division**

- **Periodic assessment**
- **Checks on Compliance**
- **Consultation with CIP Monitoring Team**

5. TRAINING & EDUCATION

- Training of high-standard principles for ethical business practices
- Requirement under CIP & IP Programmes Implementation
- Program will provide trainers with the skill set and tools to conduct training in their own economies
- In partnership with MACC, Malaysian Institute of Integrity (IIM) and regulatory bodies.



THANK YOU

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The Role of Government in Encouraging a High Standard of Ethics in the Healthcare Sector
Bali 03 Sept 2013

附件 5

Kenneth Hartigan-Go, MD
Acting Director-General
Food and Drugs Administration
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Republic of the Philippines

$C = M + D - A$

(Corruption equals monopoly plus discretion minus accountability).

Whether the activity is in the public, private, or non-profit arena, this formula of Klitgaard appears to be universal when dissecting the pathophysiology of corruption.

World Bank estimates 5% of Global GDP is lost to corruption annually. Another report conservatively estimates about 1 trillion dollars is lost annually just on bribery alone, not including other forms of corruption.

Around the world, government provides stability to society. To achieve this, governments need credibility. Reputation is an important social capital to be protected.

At the very least, government must follow the rule of law. A set of legal parameters is developed and maintained, and the violation of laws brings discord and disharmony.

But beyond the law is ethics, a higher bar to aspire to. What is legal may not necessarily be ethical. We often question how ethics, a principle, can be regulated. Ethics is something internal to a person; it connotes values and respect for the public good. But perhaps the behaviors that result from ethics, being a reflection on the issue, can be monitored and measured.

A second question to ask: between self-policing or external policing, which works better? Experience informs us that self-policing does not always work within the health professional communities. But too rigid external regulations may also stifle access to health innovations and can create unethical transactions between industry and health professionals.

One possible solution to the question of ethics is the whole-of-government approach. One branch of government with an ethical problem cannot be isolated, because it will affect other government agencies. How can government set a higher bar of ethical excellence for itself? This is not an easy solution.

Another option is the whole-of-community approach. The role of civil society as a critical watchdog on government behavior or the private sector cannot be overstated.

In the case of the Philippines, what were originally endearing traits of Philippine culture might be the etiology for ethical violations. The following are interesting socio-cultural phenomena to watch:

A. utang na loob -debt of gratitute
B. hiya-literally shame or embarrassment C. Pakikisama - shared history/common bond and fraternity D. Palakasan - i have a stronger backer than you

Any or all of these can make it difficult to do the right thing in an ethical dilemma. They often also muddle up the management of COI, even if the COI is declared transparently.

Our APEC code of ethics covers not just industry, but also health professionals that interface with the industry, and government regulators. There is therefore a necessity to demonstrate a high benchmark for govt behaviors that serve both as an aspiration and key result area within the health sector. At present, many ethical abuses in the health sector have blurred the lines because they have become traditionally accepted practice. Even respected medical practitioners engage in such practices and they become role models for younger generations. Government clinicians feel justified to participate in these practices because of their low income.

I have observed that the regulated industry, the media, society and the public sometimes place a premium on govt officials which then leads unintentionally to a chain of unfortunate events.

A. turn what should have been a servant leader government officer into a celebrity of sorts. This then evolves into a sense of entitlement.

B. then comes auditory hallucinations to aspire for higher office and more power

C. Reverse stockholm syndrome in order to defend status quo of entitlement.

There is a tendency to shoot the messenger of bad news and this discourages true whistle-blowing. Harm to whistle blowers is very real.

Leaders often forget that when they leave office and the corresponding influence of power, no one will even remember them.

Good governance is one of the six building blocks for health system strengthening. It espouses transparent and accountable management, and hence must have ethics integrated into decisions and action. While Universal health care is a worthy prize to shoot for, for instance, attaining this goal will only be enduring if it is done ethically.

Conclusion and food for thought:

APEC declaration should be constructed into a wider health systems approach. The issue is not so much policy that still needs strong advocacy, but rather, measures that can operationalize policy. Government role is to demonstrate a leadership model worth emulating and above reproach.

Thank you.

AIM WORKING PAPER SERIES

BUSINESS AND DEVELOPMENT RESEARCH

A Framework to Promote Good Governance in Healthcare

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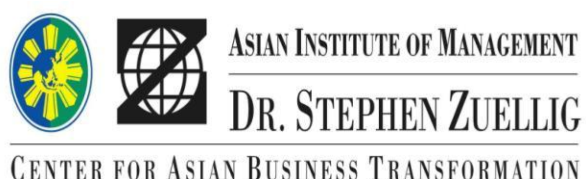

A Framework to Promote Good Governance in Healthcare

Kenneth Y. Hartigan-Go
Marian Theresia Valera
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JULY 2013

ABSTRACT

This paper aims to give an overview of the corruption and ethical dilemmas in the Philippine healthcare system and to provide a framework of strategies and solutions in order to promote good governance in the health sector. In its complexity, our healthcare system is full of vulnerable areas for corruption; as such, inefficiencies affect both the delivery and cost of healthcare. The key to combat this hounding dilemma is to ensure transparency, create accountability, and improve governance in the health sector.

The contents of this paper is limited to the results of the two Good Governance in Health (GGH) Fora that AIM Dr. Zuellig Center for Asian Business Transformation and the Hills Program on Governance through the Ramon V. del Rosario, Sr. - C.V. Starr Center for Corporate Governance jointly conducted last May 10, 2011 and March 26, 2012, respectively. The first forum focused on mapping corruption cases and ethical dilemmas in healthcare, while the second forum involved the formulation of solutions and identification of best practices in response to the cases. This paper serves as the final output of these activities.

* The paper is a product of independent research work commissioned by the authors, which were also based on the findings and results of the two GGH Fora. The authors are grateful to Atty. Angela G. Garcia, JD for her invaluable insights in the development of this paper. They also extend their thanks to Ms. Liza M. Constantino for editorial assistance and to all the participants and resource speakers of the GGH Fora. The views expressed in this paper do not necessarily reflect the views and policies of the Asian Institute of Management.

A FRAMEWORK TO PROMOTE GOOD GOVERNANCE IN HEALTHCARE

THE PHILIPPINE HEALTH SYSTEM

The Local Government Code of 1991 mandated what is now known as the devolution of health services from the Department of Health (DOH) to Local Government Units (LGUs). From a district health system, which was focused on providing primary and secondary health service provision from the central health level to the local district level (Dorotan and Mogyorosy, 2004), the Code has devolved the operation of provincial and municipal hospitals, rural health units, barangay health stations, and almost all public health programs to locally elected officials.

With the devolution of healthcare, the DOH retained control over specialized and tertiary hospitals, as well as regulatory and supervisory functions over LGUs and private healthcare providers through its units and attached agencies. However, the Philippine health sector was not prepared for this transfer of power, which did not take into account the heterogeneity of local units and institutions in terms of need and capability. Thus, a few years after the Code was implemented, the Philippine healthcare system continued to be fragmented and plagued with lack of accountability and transparency.

It must be noted that although the early implementation of the devolution of Philippine health system led to its disintegration, the DOH opted eventually to reintegrate the systems by "making the devolution work". "Making the devolution work through reintegration of health system then remained the only logical policy alternative" (J. Perez, 1998). This led to the creation of the Inter Local Health Zones (ILHZs) in 1998 as a mechanism to foster greater collaboration and coordination for health. Also established was the Health Covenant, which was entered into by DOH and the Department of Interior and Local Government in 1999 to achieve universal integrated healthcare system based on inter-LGU approach. The Presidential Executive Order 205, which was issued by President Estrada in January 2000, mandated the establishment of ILHZ and Integrated (inter-LGU) Health Planning to encourage and facilitate inter-LGU cooperation for basic health service delivery. The Health Sector Reform Agenda (HSRA) was also launched by then Hon. Secretary of Health Alberto Romualdez in mid-2000 to guide the DOH in supporting the efforts of LGUs (Grundy, Healy, Gorgolon, and Sandig, 2003).

Beyond the enactment of the Code, the complex interactions and lack of coordination among institutions that constitute the Philippine health sector, compounded by leakages in the

system and weak monitoring mechanisms, are perceived to have led to significant levels of corruption within the health sector and to the ethical dilemmas faced by health sector actors and stakeholders.

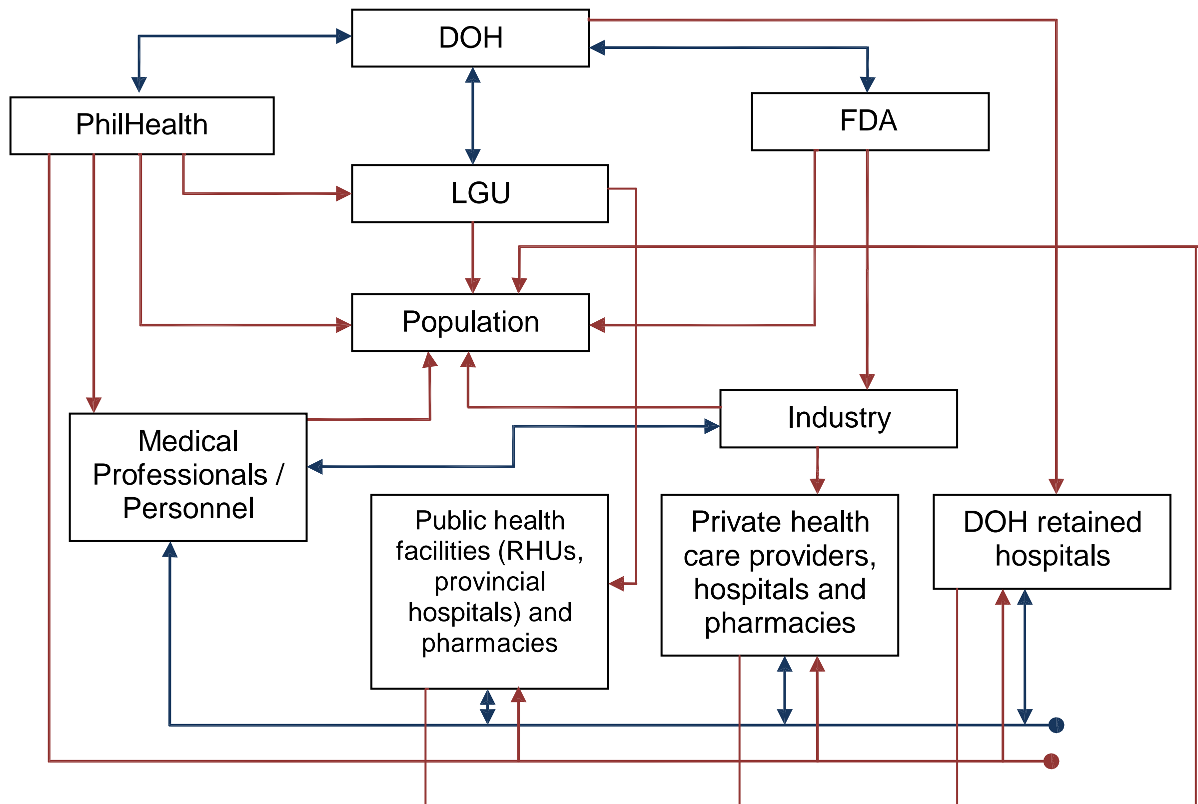
MAPPING OF STAKEHOLDER RELATIONSHIPS

There are four major government institutions responsible for the delivery of healthcare goods and services in the Philippines. They are as follows:

The Department of Health is the principal health agency in the country, responsible for ensuring access to basic public health services for all Filipinos. The DOH is composed of 24 units and central bureaus under the Central Office, 8 attached agencies, 16 regional Centers for Health Development (CHD), and 72 retained specialized and tertiary hospitals. The main function of the DOH is to organize programs that will promote health, formulate solutions to emerging health situations, develop national plans, technical standards and guidelines on health, and regulate all health services and products.

The Food and Drugs Administration (FDA) is the lead DOH unit responsible for the protection of Filipino's right to health through the establishment and maintenance of an effective health products regulatory system. The FDA Act of 2009 combined the Bureau of Food and Drugs and the Bureau of Health Devices and Technology, giving the FDA regulatory functions over food, drugs, medical devices, cosmetics, household hazardous substances, as well as radiation devices and facilities. The Act also granted the director of the FDA quasi-judicial powers to confiscate goods, shut down operations, or close down establishments that do not meet the standards set by the unit.

Figure 1: Mapping of stakeholders relationships in the delivery of health goods and service



PhilHealth, an attached agency of the DOH, was instituted as mandated by RA 7875 to provide health insurance coverage for all citizens of the Philippines. PhilHealth works directly with the LGUs in the identification and enrollment of indigents and those belonging to the informal sector. In turn, the LGUs receive capitation payments from PhilHealth. This capitation scheme aims to improve the relationship between the institution and LGUs, and ultimately, to increase PhilHealth enrollment. Capitation payments can also be used for the improvement of their health facilities and services. Lastly, PhilHealth plays an integral role in ensuring the provision of quality health services by serving as the main agency that grants accreditation to medical professionals and health facilities.

Due to the devolution of health services, the responsibility of providing the most essential healthcare services have been transferred from the DOH Central Office to local government units and their local health institutions. The Code also granted administrative autonomy to LGUs, enabling them to raise local revenues, to borrow and to determine expenditures on healthcare (Grundy et al, 2003). Local health sector budgets were also integrated in the internal revenue

allotment (IRA) received by LGUs, making health expenditures dependent on the allotment of the elected Local Chief Executive (LCE).

In 2011, the Philippine Government launched a nationwide Universal Health Care initiative called "Kalusugan Pangkalahatan" (KP). The program seeks to improve health service utilization and financial risk protection, assist the government in attaining its Millennium Development Goals (MDGs), and improve public health infrastructure through public-private partnerships. Expansions in the national government's budget for health, as well as local government involvement in the program are expected, as KP scales up its efforts to promote equitable and accessible healthcare for all Filipinos. Thus, interactions and transactions between all the stakeholders in the health sector are anticipated to increase, and so will opportunities for potential abuse and eliciting if proper mechanisms are not put in place.

ETHICAL DILEMMAS AND INEFFICIENCIES IN THE HEALTH SECTOR

Health expenditure increases as a country becomes more financially, technologically and economically developed. This area of expenditure also becomes vulnerable to corruption, which would greatly affect provision and management of healthcare. This erodes public trust in government institutions and may put patients in perilous situations.

On the other hand, deviations from ethics and systematic inefficiencies, which may not always be considered as acts of corruption, are seeds leading to the pathogenesis of corruption. It is a complex phenomenon and should be a concern under health governance, one of the six building blocks of health reforms that contribute to health systems strengthening.

AREAS OF VULNERABILITY IN THE PHILIPPINE HEALTH SECTOR

Within the complex interactions that comprise the Philippine health system, several areas stand out as possible areas of corruption and ethical dilemmas.

Local Government

Case 1: Unfair allocation of resources due to personal biases

Inequity in the sharing of capitation funds and the allocation of the IRA for health persists due to the discretionary power given to LCEs. Cases of delays in the provision of health goods have been identified as resulting from the relationship dynamics of the mayor and the municipal health officer (MHO). Instances exist where purchase requests for medical supplies have been put on hold if the MHO was not in good terms with the mayor.

Case 2: Misuse of resources for political gain

LCEs have found a way to use the provision of healthcare to their political advantage. The proliferation of political indigents, or the non-poor households who are enrolled in the PhilHealth Sponsored Program (SP), has been correlated with political gain.[1] The enrollment of PhilHealth members is fueled by political motives instead of a genuine intention to provide health coverage for the poor. Budgets for drugs and medicines, which are supposed to be included in the operating expenses of municipal health offices, are redirected to the budget of LCEs. This gives the LCEs full control over the provision of medicines, which are then distributed in city hall offices for political recall. Thus, the supposed budget for the promotion of public health is undermined by unethical officials for their own benefit.

[1] Capuno, Joseph J., Quimbo, Stella A., Tan, Jr. Carlos Antonio R., and Kraft, Aleli D. The Poor, the Politician, and the Political Indigents: The Case of the PhilHealth Sponsored Program, 2011. UP School of Economics and Philippine Center for Economic Development, Friday Seminar Series, March 18, 2011.

Case 3: Fund leakages

It has been noted that the public bidding component of the Republic Act 9184, also known as the Government Procurement Reform Act, is not strictly followed, and preference is given to contracts that can produce kickbacks for the approving official. Bribery is said to be present in the delivery of municipal-purchased drugs, and most goods are received even if they do not meet the terms and conditions of contracts. Connivance with contractors who engage in bidding for health infrastructure projects is also observed, as most officials receive monetary rewards in exchange. As an example, the 2010 Commission on Audit (COA) Report shows that there were lapses in the identification of selected bidders and the awarding of winners for the conduct of Trainings and Management of TB in Children for physicians and nurses in CY 2009 with a total cost of P2.47 million. The decision of the Bids and Awards Committee (BAC) to award the "Contracts" to four selected hotels instead of the bidder with Lowest Calculated Bid appears to have been unwarranted and not meritorious in violation of the prohibition in Section 53 of R.A. 9184. Cases have also been documented where the hiring and training of health personnel are not based on required skill or need but on nepotism and political considerations.

Health Regulatory System

Case 1: Regulatory capture

The capacity of the FDA to perform their duty is continuously being hampered by regulatory capture. The acceptance of bribes to advance commercial interest by accelerating the approval of products and establishments has been plaguing the department since its establishment. While steps are being undertaken to accelerate the integrity development program within the FDA, other forms of pressure from industry continue to erode the credibility of the administration. For example, strategic harassment lawsuits are frequently filed against regulators who, being public servants, do not have the means to avail of legal support.

Medical Practitioners

Case 1: Conflict of interest

In order to increase earnings, most physicians enter into various income-generating activities such as investing in the private sector. It is common for physicians to establish financial affiliations with private pharmacies, diagnostic clinics and other private health facilities. An analysis conducted on the risk of perverse financial incentives emerging from physician-pharmacy ownership showed that public physician-linked pharmacies appear to persuade their patients to use their pharmacies, and their patients appear to spend more on medication (James et al, 2009). Other forms include the prescription and dispensing of supplements by physicians at their clinics, and over-charging for vaccinations and other medications. This is one of the factors that make the health sector vulnerable to corruption. Physicians know more about health issues or illnesses than patients do, while private pharmacies or health enterprises know more about their products than government officials; such knowledge can be used for their personal gain.

Case 2: Tax noncompliance

Leakages and inefficiencies in the Philippine tax system, together with the lack of auditing and monitoring procedures, allow for instances of corruption to occur. Often, physicians are caught not properly complying with the provisions of the tax code by falsifying or failing to issue receipts for professional fees, or by under-declaring their income statements.

Case 3: Duality of practice

Low public sector salaries, relative to the private sector, often drive physicians to engage in private practice to supplement their meager salaries. This results in doctors spending official time in private practices, utilizing the public system to refer patients to their private practice, and having high rates of absenteeism[2].

[2] Corruption in the health sector, U4 Issue 2008:10, Anti-corruption Resource Centre, Updated November 2008.

Commercial Enterprises

Case 1: Unethical promotion

Alliances between physicians and commercial enterprises often affect the care of patients and the reputation of the medical profession. In the pharmaceutical industry for example, physicians are often granted special privileges with the aim of influencing their prescription behavior, to instill brand loyalty, or worse – to request the inclusion of their sponsors' products to hospital formularies. Such privileges granted by the industry include paid trips abroad for meetings and conferences, consultancies on advisory boards, and receipt of research funding, gifts and free medicine samples.

Health Insurance

Case 1: Provider-induced fraud

Due to the paper-and-pen system of processing health insurance claims, health professionals can get away with fraudulent practices. Provider-induced fraud include the phenomenon of phantom billing, or the performance of unnecessary procedures to be included in the claims application of the patient (in order to get more reimbursements from the insurer). Other practices include the upcoding of bills by using billing codes for procedures that are more expensive than what was performed or required by the patient, and the billing of free services and falsification of place-of-service documents.

THE EFFECTS OF CORRUPTION AND LACK OF TRANSPARENCY IN THE HEALTH SECTOR

The more a country becomes developed, the higher its expenditure on health becomes. Without transparency and accountability mechanisms in place, there may be more opportunities for abuse and eliciting by people who are in the position to commit unethical practices. In 2005, it was documented that officials and employees of LGUs were estimated to receive kickbacks from the

purchase of medicines amounting to 10 to 70 percent of the contract price[3], thereby diverting local funds to those in positions of power. We see a case where corruption erodes legitimacy and public trust in government institutions.

Corruption and wastage of resources increase inefficiencies in the financial management of healthcare. For instance, during the second Good Governance Forum at the Asian Institute of Management, Leonor Magtolis Briones shared COA findings that estimated that the loss incurred by the government due to expired, unnecessary and overpriced laboratory reagents totaled PhP 6.84 million in 2010. The reasons cited was the lack of prudence in the procurement and management of laboratory supplies by hospital officials, which is in violation of R.A. No. 3019 or the Anti-Graft and Corrupt Practices Act.[4] More importantly, it has a negative impact on access, quality and equity in health systems, and has serious implications on universal healthcare reform and the attainment of health-related MDGs.

Minimizing the effects of both corruption and lack of transparency in the health sector will take much time and effort especially on the part of the government. The right process of bidding, and the appropriate use and monitoring of health related-funds are few obvious steps that should be taken. In addressing the said problems, there should be no other goal than to provide the public with better healthcare services, and ultimately, better health.

PROMOTING GOOD GOVERNANCE IN HEALTH SYSTEM

Governance, as defined by the United Nations Development Programme, is the exercise of political, economic, and administrative authority to manage a nation's affairs. It embraces all methods – good and bad – that societies use to distribute power and manage public resources and problems (UNDP, 1997). On the other hand, the Asian Development Bank describes governance as the institutionalization of a system through which citizens, institutions, organizations, and groups in a society articulate their interests, exercise their rights, and meditate their differences in

[3] Olarte, Avigail M. and Chua, Yvonne T. Up to 70% of Local Health Funds Lost to Corruption. Philippine Center for Investigative Journalism, May 2-4. 2005.
[4] Leonor Magtolis Briones served as the main speaker during Solutions Generation Forum, conducted by the AIM Zuellig Center for Asian Business Transformation, in partnership with the AIM Hills Program on Governance through the RVR – C.V. Starr Center for Corporate Governance, on May 26, 2012. She presented "Corruption in the Philippines: Implications for Health". Dr. Briones is recognized as the Lead Convenor of Social Watch.

pursuit of collective good. ADB identified the basic principles of good governance as Accountability *(making public officials answerable for government behavior and responsive to the entity from which they derive authority)*, Participation *(refers to enhancing people's access to and influence on public policy processes)*, Predictability *(existence of laws, regulations and policies to regulate society and the fair and consistent application of these),* and Transparency *(availability of information to the general public and clear government rules, regulations, and decisions)* (ADB, 2005).[5]

One prevailing problem that undermines good governance is corruption. Robert Klitgaard, a renowned expert on corruption, explained how corruption happens through the following formula: C = M + D - A *(Corruption equals monopoly plus discretion minus accountability).*

Whether the activity is public, private, or non-profit, conducted in the Philippines or abroad, corruption will be present when an entity with monopoly over a good or service has the discretion on its distribution, and is not held accountable for wrongdoing. The health sector is not exempt to corruption. Although corruption in the health sector is vast and difficult to determine, its impact on the health of the community cannot be denied.

A report from Transparency International shows that the poor is disproportionately affected by corruption in the health sector as they are less able to offer small bribes for fee-for-services and are unable to pay for private alternatives. In the Philippines, the poor and middle-income wait longer at public clinics than their more affluent counterparts.

The health system itself is complex in nature due to the huge number of parties involved. There are policies and legal frameworks in place to regulate the relationship of these actors, but oftentimes, due to inefficiencies, lack of information, and conflicts of interest, opportunities for bribing health regulators do arise. The primary step in dealing with these, then, is to identify and closely examine the roles and relationships among medical suppliers, health professionals, policy makers and even the people's organizations or non-government organizations. Furthermore, there is a need to simplify and aggressively monitor regulatory procedures because it is through

[5] Country Governance Assessment: Philippines, ADB 2005, as also cited in Brillantes, Jr. Alex B., Fernandez Maricel. Is there a Philippine Public Administration? Or Better Still, For Whom is Philippine Administration?, Philippine Journal of Public Administration, Volume LII April-October 2008, Numbers 2-4. 2008.

such processes that informal payments, issues in procurement and distribution of drugs or medical supplies, and similar scenarios lead to abuse of power for private gains or embezzlement of health-related funds.[6]

The Department of Health, being the lead agency in promoting health through the provision of healthcare services and health-related programs, should include explicitly laid out anti-corruption measures in its national agenda. Strong leadership and political will are required to champion good governance in health, and DOH should promote that leadership. This will entail engaging the officials and employees of the health sector – whether in government or private health institutions – to provide services with utmost integrity, making them aware of the punishments involved in cases of violation.

At the local level, delegating specific executive powers to other health players may help bring more transparency and accountability in the provision of public health services. For instance, Inter Local Health Zones (ILHZs) proved to be advantageous in capacitating LGUs in the delivery of basic health services to its constituents. DOH defines ILHZ as *to be any form of organized arrangement for coordinating the operations of an array and hierarchy of health providers and facilities, which typically includes primary health providers, core referral hospitals and end-referral hospitals, jointly serving a common population within a local geographic area under the jurisdictions of more than one local government.* ILHZs are formed by several contiguous LGUs coming together with the common aim of better delivery of health services to the people (especially in the provinces), as well as better management of health resources. As such, one possible way of minimizing corruption and patronizing health services is for the national government to appropriate a certain portion of an LGU's IRA directly to the accredited ILHZs.

The Local Health Boards (LHBs), as a local special body (LSB) mandated by the Local Government Code of 1991, are not fully utilized, or worse, not even constituted by the LGUs. LHBs serve as a venue for citizen participation in local health concerns; as such it might as well serve as vanguard for anti-corruption in the health sector. Health-related programs of DOH like the "Botika ng Barangay" should also be strengthened. It should be emphasized that the

[6] DFID How to Note: Addressing Corruption in the Health Sector, DFID Practice Paper, Department for International Development, United Kingdom, November 2010.

barangay is the front-runner in the delivery of health services to the people. Therefore, programs and projects implemented at its level would be more effective and efficient as it is the barangay that knows the specific health needs of its constituents.

On the other hand, politics in the distribution of PhilHealth cards can be minimized if the agency itself will be the one responsible for the distribution of the cards. In this specific case, the role of the LGUs should be reduced to identifying possible beneficiaries.

Conversely, the private sector and NGOs that employ health professionals, pharmacists, medical suppliers and other allied health professionals should strictly implement an effective anti-corruption mechanism where a Code of Conduct and a clear policy outlining rules on procurement, receiving and giving gifts, and anti-bribery should be in place. External audit should also be required to ensure checks and balances.★

There is also a need to revisit the existing medical curriculum to reflect the principles of good governance in health and injecting the importance and value of providing good health services to the people. This will prove to have a lasting impact on how future medical professionals and personnel conduct themselves when faced with ethical dilemmas or even corruption. As for students and young professionals alike, creating a venue for them to band together and become advocates for good governance is also viable step to take.

Furthermore, to promote transparency and accountability in the health sector, information on health should be made available and easily accessible for public scrutiny. This should include budget and health funds, employee performance, statistics on health and health outcomes, health program assessments, health delivery processes, policies indicating rewards and punishments, and other information that involves regulatory and auditing processes. Opening such information to the public will introduce avenues for oversight. It will widen citizens' participation in health-related initiatives, leading to equal involvement among the three sectors - the public, private, and third sector - which comprises the paradigm of governance.

The following section provides more strategies to combat corruption in the health sector:

★Corruption in Health Sector, Based on Executive Summary and Foreword by Mary Robison, Corruption and Health: Global Corruption Report 2006, Transparency International, February 2006.

SOLUTIONS TO COMBAT CORRUPTION IN THE HEALTH SECTOR

The key to providing concrete solutions against corruption is to maintain transparency through consultations and cooperation between the industry, civil society and the government. This involves building stronger ties between health regulatory agencies and institutions concerned with fighting corruption and promoting good governance.

a. *Establishment of an incentive and punishment system to ensure compliance and accountability.*

Developing mechanisms that would encourage key players in the health sector to promote compliance and accountability within their organizations would substantially impact their attitude towards corruption. This translates to improving the rewards system to specific actions that clearly and greatly manifests integrity and accountability among health employees – for instance, recognizing their efforts through promotions or bonuses. Penalizing corrupt practices through suspension, dismissal, transfer of departments, and other forms of punishment should be explicit in the rules to warn and guide health sector employees of the consequences of any unethical behavior and corrupt practices.[8]

The government can better serve this function by strengthening the authority of the Civil Service Commission and other institutions in implementing integrated rewards and incentives programs.

b. *Improvement of monitoring and evaluation systems and initiating checks and balances.*

Encouraging extensive monitoring procedures, breaking the culture of silence in institutions by establishing a reporting and complaint mechanism, applying the use of modern technology, and finally, enticing citizen participation can discourage stakeholders from engaging in practices that corrupt the health system.

As an example, improving the database management, surveillance systems and computerizing health insurance claims in hospitals will protect health insurance providers such as PhilHealth from issues of fraudulent practices. Only procedures done on the patient

[8] Fighting Corruption in the Health Sector Methods Tools, and Good Practices, United Nations Development Programme Bureau for Development Policy, New York USA, October 2011.

and those reported by the concerned hospital departments will be reflected in the database, thereby preventing document falsification and billing manipulation.

There is also a resounding need for an effective independent oversight mechanism. This may mean an external oversight committee that would investigate, monitor, and evaluate health-related processes to identify failures and inefficiencies, including assessing complaints about unsatisfactory services. An external audit is also necessary to regularly review and check government and private transactions concerning healthcare resources. Independent oversight mechanisms should provide recommendations for improvement of governance in health.

c. Organizational development and capacity building programs as a solution to inefficiencies.

Inefficiencies within organizations often lead to practices that result in wastage, loss of productivity and eventual ethical dilemmas. In the same way, deliberate attempts by individuals to disregard inefficiencies could be regarded as an act that promotes corruption.

Several steps to address inefficiencies involve reviewing the existing organizational model and comparing it with models that work. For example, the government adapting successful systems developed by private institutions could be an area for a public-private partnership. Another effective strategy would be to expand capacity-building efforts that will empower leaders to effect change by improving systems and empowering employees to con

tribute to efficiency efforts. Regular training of health employees that would not only improve their skills but remind them of their responsibilities to support the health sector's aim of preventing and eliminating unethical conduct and corruption should be initiated by their respective institutions.

d. Promote the development and application of evidence-based research.

Allocation problems often occur when resources are directed to areas without considering performance or need. Targets are often missed when results are not measured, and projects are given priority without forecasting impact. Therefore, compelling evidence should be produced to validate whether or not programs have been able to deliver intended outcomes;

resources are equitably distributed; and public funds are efficiently utilized. In addition, evidence from such research should be used and tied-up in the policy and decision-making process. To date, two rigorous reforms in primary healthcare have been enacted, yet there has not been a comprehensive impact evaluation of the reforms.

Conversely, increasing support in improving data collection and access, investing in human resources and strengthening the pool of experts that will conduct evidence-based research in health, as well as educating legislators on healthcare issues, will significantly improve the country's approach to policy-making.

The 1987 Philippine Constitution Article II Section 15 states that, *"The State shall protect and promote the right to health of the people and instill health consciousness among them"*. Indeed health consciousness is achieved by knowing the needs of our countrymen. In June 2011, the Philippine National Health Research System (PNHRS) Act of 2010 was enacted.[9] Part of PNHRS service includes securing sustainable financing for health and development and deepening the involvement of stakeholders. Health research is important in developing and improving health strategies, policies and service delivery. PNHRS Act of
2010, through the use of Philippine National Health Research Fund, seeks to support quality ethical health research and its application to health and development.

e. Improving transparency in government transactions and encouraging participation through access to information.

The Department of Health can contribute to transparency efforts by making data readily available to the public. Regularly publishing information online such as health statistics, relevant presentations, news on health, and even the prices and quality of healthcare goods will keep the public informed. A powerful health information system that is regularly monitored and updated is necessary to improve transparency.

It has also been suggested that line item budgets by government offices be made accessible to the public. This will improve transparency, strengthen public fund management

[9] HB 4207 Philippine National Health Research System Act of 2010, Agham party List, Abigail Monic Ponceca Ellis, June 28, 2011.

and empower the citizens to engage in participatory budgeting. Moreover, transparency should be extended to government procurements, contracts, and grants by keeping an open repository of all contracts concerning government transactions in healthcare, including that of existing Official Development Assistance loans. In terms of procurements, market forces should be allowed to take control by upholding the provisions and implementing rules and regulations of R.A. 9184. A strict "no gift giving policy" should also be enforced.

f. ***Influencing the government to make healthcare a priority*.**

The Local Government Code was envisioned to promote greater local fiscal autonomy by promulgating an automatic and mandatory distribution of IRA to the different LGUs in the Philippines. In addition to this, LGUs were granted higher shares in national government revenues, bestowed broader revenue-generating powers and allowed to enter into cooperative undertakings with the private sector or other LGUs[10].

Similarly, fund allocations for healthcare are discretionary and dependent on the priority given by LGUs to meet health outcomes. This is one source of inequity, as some LGUs might allot more for the health needs of their constituents compared to others. Educating LCEs to give priority to health programs, and encouraging them to a fixed minimum budget allocation specifically for health-related matters should be a priority. The implementation of the LGU scorecard would also add the necessary pressure for them to meet national and local health targets by giving priority to the provision of healthcare.

Harmonizing national budget sources for health (e.g., PAGCOR, and eventually the revenues from sin tax), as well as adopting a participatory bottom-up approach, will also benefit the poorest LGUs. Examining their priorities and providing them with support for health projects that they cannot otherwise fund at the local level will also contribute to
meeting national targets.

[10] Capuno in Smoke, Paul and Kim,Yun-Hwan, Intergovernmental Fiscal Transfers in Asia: Current Practice and Challenges for the Future, edited by Smoke and Kim, Manila: Asian Development Bank, December 2002.

g. Strengthening the health regulatory system.

Allowing the FDA to retain its income will significantly improve the service and service capacity of the health regulatory system. This includes hiring more regulations officers and acquiring more state-of-the-art equipment to conduct faster and more precise assessments of products. Moreover, providing regulators with access to legal support will help protect them from harassment lawsuits and will improve their policing powers in enforcing their mandated responsibility to protect the public from dangerous products, false claims or industry pressures.

h. Influencing health professionals and personnel to abide by ethical practices.

Implementing standards in the development of clinical practice guidelines and standard operating procedures for health professionals is an effective way to promote ethical practice. Often, medical professionals rationalize their unethical behavior if flaws are found in the system at the outset. The standardization should emanate from key government agencies such as the DOH and PhilHealth in collaboration with all relevant medical societies.

i. Creating partnerships and areas of cooperation between the government and medical associations/societies to ensure tax-compliance among physicians.

Beyond reliance in our current tax system, the government, through the Bureau of Internal Revenue (BIR), should continue to work with various medical societies in ensuring that physicians are paying the right amount of taxes. In doing so, BIR should commit itself to conduct information dissemination activities on a country-wide basis to the members of different medical associations with respect to matters on tax compliance. It may not be an absolute solution, but the organizational commitment of these associations will help alleviate instances of corruption among their individual members.

j. Providing proper remuneration and incentives for public health workers.

Ensuring that public health workers are competitively compensated, providing exemptions on the standardized salary law for health professionals, and giving incentives to

those situated in far-flung areas will prevent duality of practice and promote the equitable distribution of healthcare resources and services.

CONCLUSION

The effective and efficient provision of healthcare services has been a major challenge to the national and local governments alike. Budget constraints, insufficient medical facilities and equipments, and the medical professional brain drain are among others. These challenges are seen to be compounded by malpractices, ethical dilemmas, and corruption in the health sector. As a result, it is the citizen that stands on the losing end as receivers and beneficiaries of substandard health services. True to the point, when there is corruption, it is the people – particularly the poor and the less privileged – that are most affected.

Despite these, the future of the Philippine health sector remains promising – that is, with the implementation of needed reforms and anti-corruption safeguards. This paper has tackled several situations and cases-in-point on how corruption and ethical dilemmas in the health sector can be battled; how the health sector can be better capacitated; and as a whole, how to improve the current health sector status of the country. Some of these can be achieved and implemented in the short term period, while most offer medium and long-term policy solutions.

Following the governance paradigm, collaboration between the government, private sector and civil society is needed to see these health reforms and anti-corruption mechanisms into reality. The government should efficiently implement better policies that gear towards good governance in health. It should also look at partnerships and ventures with the private sector in the delivery of health services; and the civil society should continuously act as the public watchdog, safeguarding the interests especially of the poor, marginalized, and less privileged.

References

Brillantes, Jr. Alex B., Fernandez Maricel. Is there a Philippine Public Administration? Or Better Still, For Whom is Philippine Administration?, Philippine Journal of Public Administration, Volume LII April-October 2008, Numbers 2-4.

Briones, Leonor Magtolis. Corruption in the Philippines: Implications for Health. Presentation during the Solutions Generation Forum, AIM, March 26, 2012.

Capuno, Joseph J., Quimbo, Stella A., Tan, Jr. Carlos Antonio R., and Kraft, Aleli D. The Poor, the Politician, and the Political Indigents: The Case of the PhilHealth Sponsored Program, 2011. UP School of Economics and Philippine Center for Economic Development, Friday Seminar Series, March 18, 2011.

Capuno in Smoke, Paul and Kim, Yun-Hwan, Intergovernmental Fiscal Transfers in Asia: Current Practice and Challenges for the Future, edited by Smoke and Kim, Manila: Asian Development Bank, December 2002.

Corruption in Health Sector, *Based on Executive Summary and Foreword by Mary Robison, Corruption and Health: Global Corruption Report 2006,* Transparency International, February 2006. http://unpan1.un.org/intradoc/groups/public/documents/unssc/unpan022985.pdf, Retrieved on July 15, 2012.

Corruption in the health sector, U4 Issue 2008:10, Anti-corruption Resource Centre, Updated November 2008. http://www.U4.no, Retrieved on November 21, 2011.

Country Governance Assessment: Philippines, Asian Development Bank, Philippines: ADB, 2005.

DFID How to Note: Addressing Corruption in the Health Sector, DFID Practice Paper, Department for International Development, United Kingdom, November 2010. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/67659/How-to-Note-corruption-health.pdf, Retrieved on July 15, 2012.

Dorotan, Eddie G., and Mogyorosy, Zsolt. Making Your Local Health System Work – A Resource book on the Local Health System Development, Manila: German Agency for Technical Cooperation (GTZ), 2004.

Fighting Corruption in the Health Sector *Methods Tools, and Good Practices*, United Nations Development Programme Bureau for Development Policy, New York USA, October 2011. http://www.undp.org/content/dam/undp/library/Democratic% 20Governance/IP/Anticorru ption%20Methods%20and%20Tools%20in%20Health% 20Lo%20Res%20final.pdf, Retrieved on August 15, 2012.

Grundy J, Healy V, Gorgolon L, and Sandig E., Overview of devolution of health services in the Philippines. International Electronic Journal of Rural and Remote Health Research, Education, Practice and Policy, 2003. http://www.rrh.org.au/publishedarticles/article_print_220.pdf, Retrieved on October 15, 2011.

HB 4207 Philippine National Health Research System Act of 2010, Agham party List, Abigail Monic Ponceca Ellis, June 28, 2011. http://www.agham.org.ph/legislation/bills/authored/hb-4207-philippine-national-health-research-system-act-of-2010.html, Retrieved on September 8, 2012.

James, Christ D., Peabody, John, Solon, Orville, Quimbo, Stella, and Hanson, Kara. An Unhealthy Public-Private Tension: Pharmacy Ownership, Prescribing, and Spending in the Philippines. Health Affairs, 28, no.4 (2009):1022-1033; doi: 10.1377/hlthaff.28.4.1022.

Olarte, Avigail M. and Chua, Yvonne T. Up to 70% of Local Health Funds Lost to Corruption. Philippine Center for Investigative Journalism, May 2-4. 2005. http://pcij.org/stories/2005/health.html, Retrieved on January 20, 2012.

Reconceptualising Governance. Discussion Paper Series No. 2. Management Development and Governance Division, Bureau for Policy and Programme Support, United Nations Development Programme, New York, January 1997.

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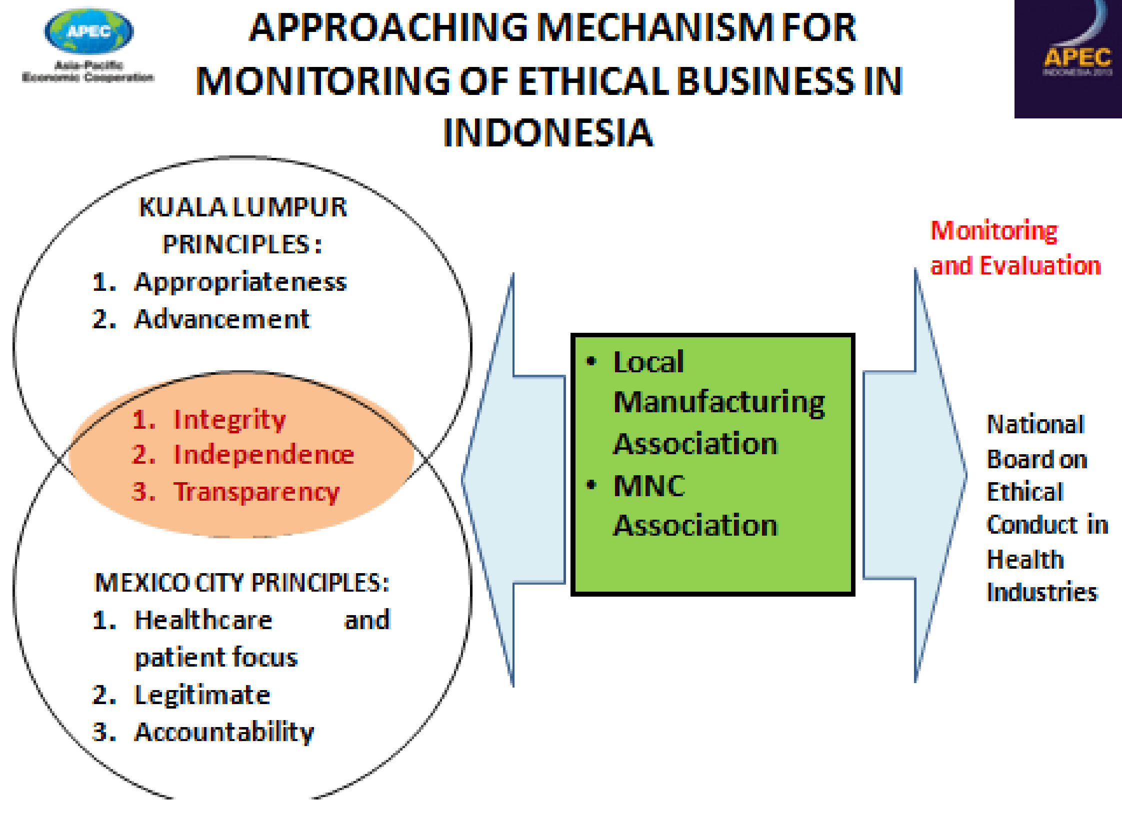
The Role of Government in Encouraging a High Standard of Ethics in the Healthcare Sector: Indonesia Experience
Prof. Agus Purwadianto
Senior Adviser to the Minister of Health for Health Technology & Globalization, Ministry of Health, Indonesia
Bali, 3 September 2013


APEC
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APPROACHING MECHANISM FOR MONITORING OF ETHICAL BUSINESS IN INDONESIA
APEC
INDONESIA 2013
KUALA LUMPUR PRINCIPLES:
1. Appropriateness
2. Advancement
1. Integrity
2. Independence
3. Transparency
MEXICO CITY PRINCIPLES:
1. Healthcare and patient focus
2. Legitimate
3. Accountability
• Local Manufacturing Association
• MNC Association
Monitoring and Evaluation
National Board on Ethical Conduct in Health Industries

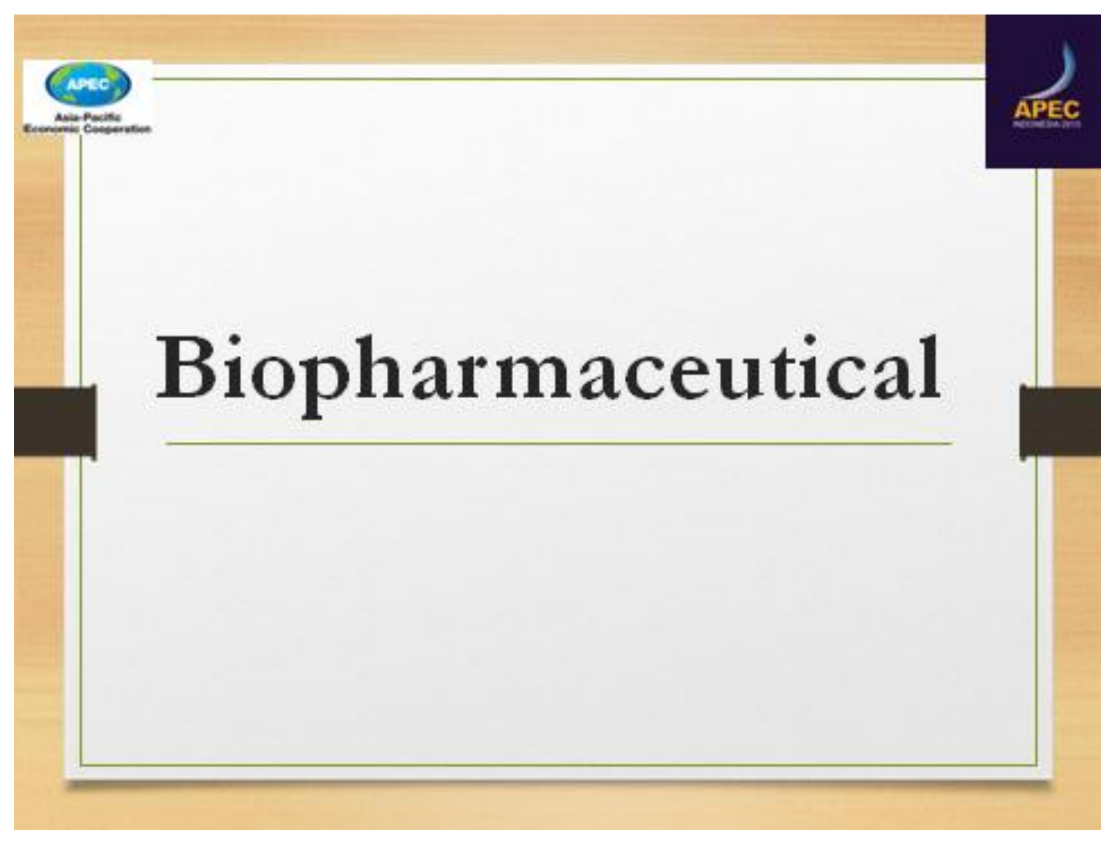
Comparison between KL Principle & Code of conduct of Association of Medical Devices and Laboratory Indonesia

Key Content	KL Principle	Gakeslab code of conduct
Purpose of code, general provisions	✓	✓
Consulting agreement	✓	Only for research
3rd party educational program	✓	Very general
Company organized education & training	✓	Very general
Sales & promotion meeting	✓	Very general
Educational items	✓	×

Key Content	KL Principle	Gakeslab code of conduct
No gifts or entertainment	✓	Very general
Charitable donations & research & education grants	✓	Very general
Demonstration & evaluation products	✓	×
Ensuring effective code implementation	✓	✓
Trade policy for ethical trading	×	✓

Analysis

- KL principles focuses on ethical guidelines for interaction with Healthcare Professionals (i.e. Doctor)
- Gakeslab Code of Conduct focuses on ethical trade policy with the emphasis to comply with existing government regulation
- Potential issue if KL principles is adopted: managing grey area between hospitality and business ethics (as this does not appear in detail in Gakeslab Code of Conduct)
- KL principle is just guidelines, each country will have freedom to adopt the content.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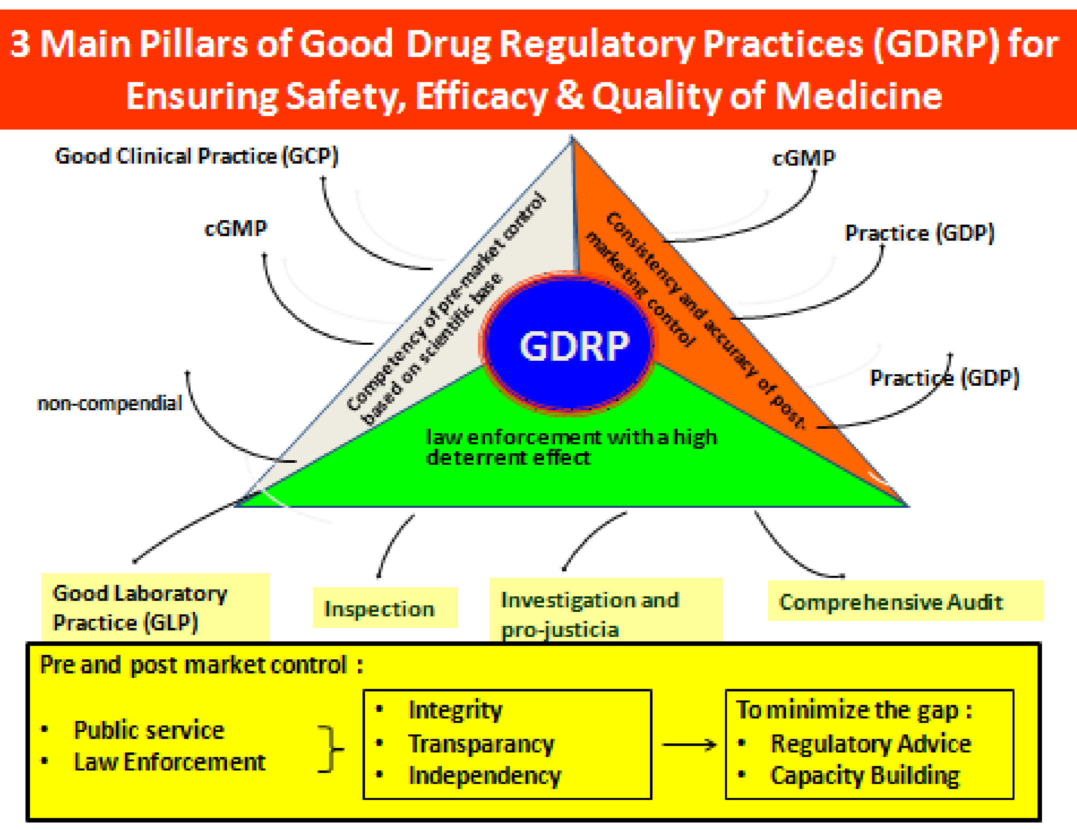
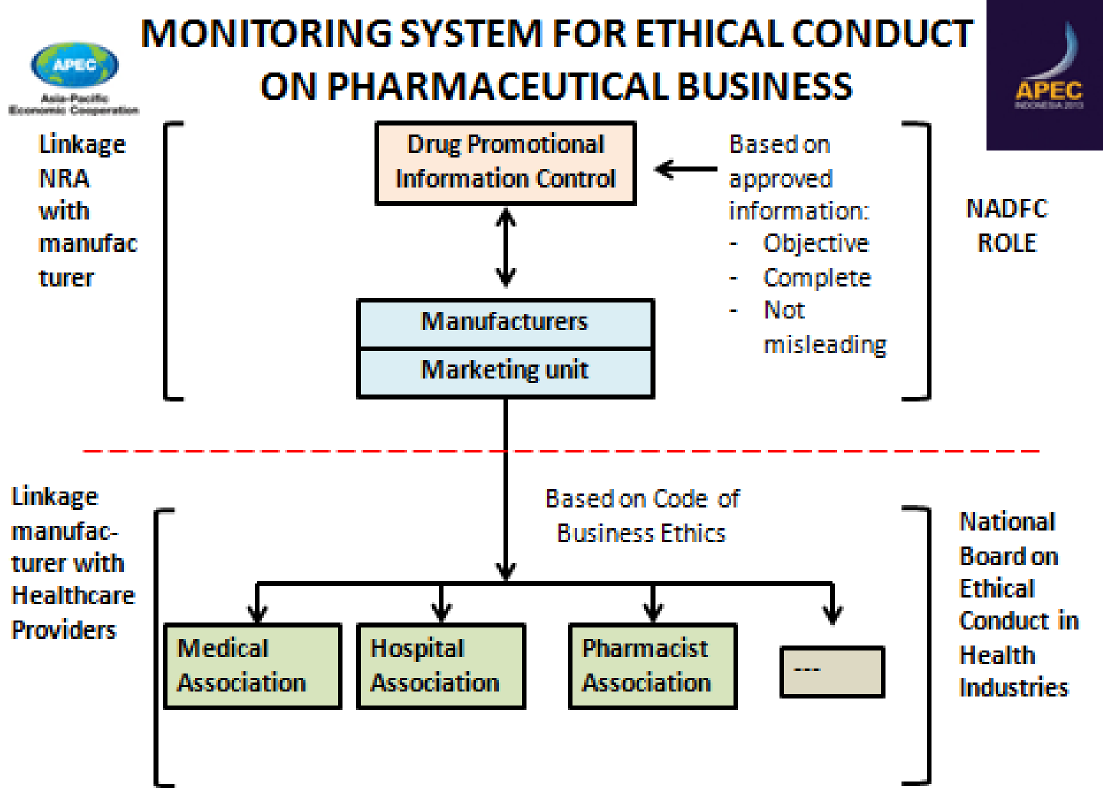
Biopharmaceutical


3 Main Pillars of Good Drug Regulatory Practices (GDRP) for Ensuring Safety, Efficacy & Quality of Medicine
Good Clinical Practice (GCP)
cGMP
cGMP
Practice (GDP)
Practice (GDP)
non-compendial
Competency of pre-market control based on scientific base
Consistency and accuracy of post-marketing control
GDRP
law enforcement with a high deterrent effect
Good Laboratory Practice (GLP)
Inspection
Investigation and pro-justicia
Comprehensive Audit
Pre and post market control :
• Public service
• Law Enforcement
• Integrity
• Transparancy
• Independency
To minimize the gap :
• Regulatory Advice
• Capacity Building



DRUG PROMOTION CONTROL (NADFC)

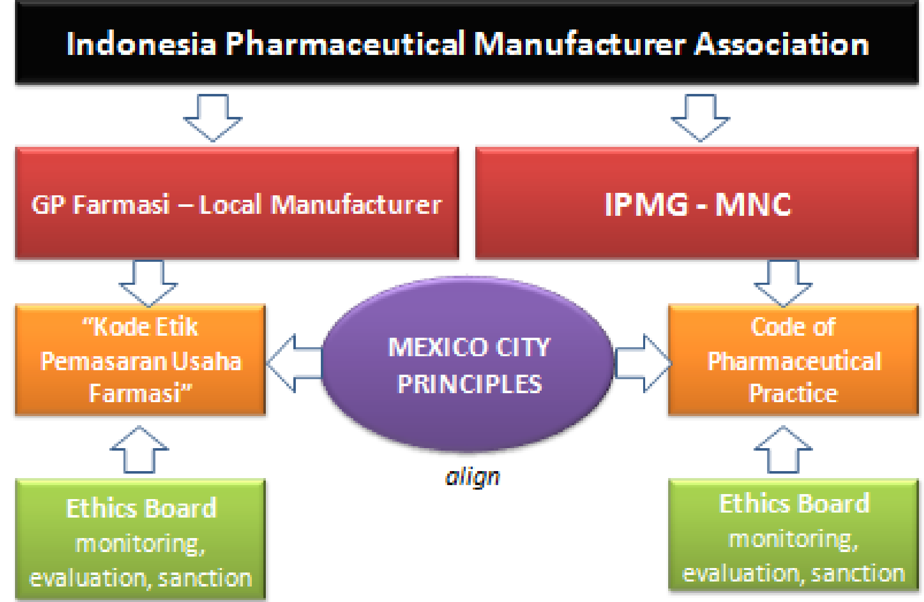
The objectives are:

- To control the consistency of approved Drug information
- To protect the public from misleading information

Mechanism:

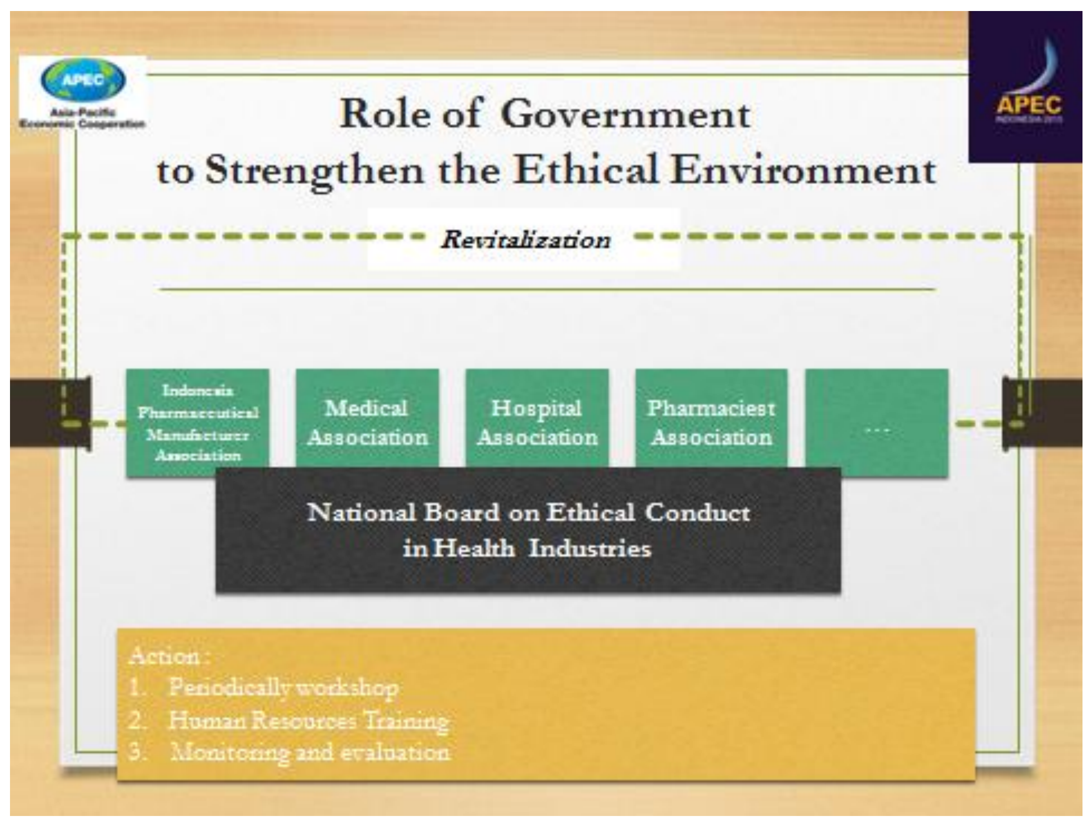
Pre- publish approval and post publish control in all mass media and distribution points

Current Condition



KODEKI (Indonesia Medical Association Code of Ethics)

- KODEKI has included Mexico City Principles in the explanation of Article 3.
- KODEKI has been legalized in the Association of Indonesian Medical Doctor on December 2012 in Makassar. It will be socialized to the 245 branches across Indonesia, 33 council meetings ethics specialists, and 17 associations of seminat.
- Since 2004, Association of Indonesian Medical Doctor and Association of Indonesian Pharmaceutical has agreed to set up a joint panel of ethics for prosecute violators of conduct of both parties.
- In 2008, a Charter of cooperation has been developed to enforce the code of ethics between two parties with the presence of Minister of Health and Head of NADFC.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Role of Government
to Strengthen the Ethical Environment
Revitalization
Indonesia Pharmaceutical Manufacturer Association
Medical Association
Hospital Association
Pharmaciest Association
...
National Board on Ethical Conduct
in Health Industries
Action :
1. Periodically workshop
2. Human Resources Training
3. Monitoring and evaluation

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Economic Cooperation
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INDONESIA 2013
Thank you
Terima kasih

The role of government in encouraging a high standard of ethics in the healthcare sector

Somsak Lolekha, MD, PhD

Thank you madam chairperson, distinguished participants , ladies and gentlemen As the president of the Medical Council of Thailand, we already have code of ethic about the relationship between physicians and healthcare industries since the year 2000. It composed of 6 articles

Article 41. Medical practitioner shall not accept money from healthcare industries except for consultation fee, honorarium for academic lecture, and research honorarium if receiving a research grant from that industry

Article 42. Medical practitioner shall not accept any gift, service, or recreation worth more than 3000 THB (US$100), except an item with academic contribution beneficial to patient service, which may be accepted in the name of his or her institution.

Article43. When being sponsored by an entrepreneur for study visit, conference attendance, or academic lecture in the country or overseas, a medical practitioner can receive only travel expense, registration fee, lecture honorarium, meal and accommodation cost for himself and only for the period of the visit, conference, or the lecture.

Article44. When being a presenter in any healthcare product advertisement, a medical practitioners shall not use the word Doctor or make the public understand that he or she is a medical practitioner.

Article 45. When speak or write about any healthcare product , the medical practitioner shall reveal his or her connection with the entrepreneur, for example , As consultant, or as co-investigator, or as a recipient of visiting, conference, or lecture subsidy.

Article 46 Royal College of specialties under medical council may formulate rules of practice for their members in agreement with the regulations in this part. If a medical practitioner does not follow this regulation and someone file a complaint to the Medical Council, he will be investigated. The punishment include warning, reprimand, suspend the license or revoke the license.

When I read the Mexico City principles for voluntary codes of business ethics in the bio pharmaceutical sector. It is acceptable and it is similar to 8th edition Code of Sales & Marketing Practices adopted by Pharmaceutical Research & Manufacturers Association (PReMA) in Thailand in 2008. To control corruption and ethic, we have to reinforce both supply and demand sides. Government pharmaceutical organization of Thailand which belonged to the government never follows code of sales and marketing practices.

Government pharmaceutical organization is not a good role model so all of the local pharmaceutical companies that sale generic drugs do not follow code of sale and marketing practice. It is a voluntary practice not compulsory. It should be law or regulation proposed by the government. Kick back is unethical

for medical practitioner in Thailand, but some pharmaceutical or medical device company select to support medical practitioners who have a lot of patients. We ask the company to support medical practitioner to attend the convention aboard by donate the money to institution or organization and let them select the appropriate doctors. It turned out that those who were selected were not the one who work in that field. They select director general or high ranking officers who know nothing about the subject in that convention. The doctors who work hard in that subject were not selected.

Should we follow France and US on Sunshine Act or physician financial transparency report? I think we should wait and see the impact on this program. There is benefit and adverse effects on this program and it has not been proved that cost of drug will be lower down. Transparency is a good thing but it must have some limit not invade privacy and confidentiality. When you pass through the security check, you don't have to undress and become naked to show your transparency. We can use other means to check. All physicians have to declare their incomes and source of their income to the Internal Revenue Service but they don't have to put their income on the website. Politicians, press, employee and NGO should show their transparency by post their source of incomes on website first.

Thank you.

APEC Healthcare Stakeholders Awareness High-Level Meeting: Fostering Ethical Environments in the Medical Device & Biopharmaceutical Sectors

The Collective Action of Chinese Taipei's Stakeholders Against Medical Corruption

Chu Kung-Mao, Director-General
Agency Against Corruption, Ministry of Justice
3 September 2013
Chinese Taipei

APEC SMEWG

Has already prescribed the ethics code for manufacturers of medical devices, bio-pharmaceuticals and for construction and engineering sectors.

Now, it is continuing to address the specific ethics code for respective member economies.

2

The Control Yuan and Legislative Yuan of Chinese Taipei

- After seeing the recent outbreak of a scandal involving bribery to the high-level management of health agencies and hospital physicians and collusion in the bidding for the procurement of medicines and medical equipment.
- They have urged the Ministry of Health and Welfare to set up stricter and clearer criteria to govern the relations between physicians and commercial enterprises.

3

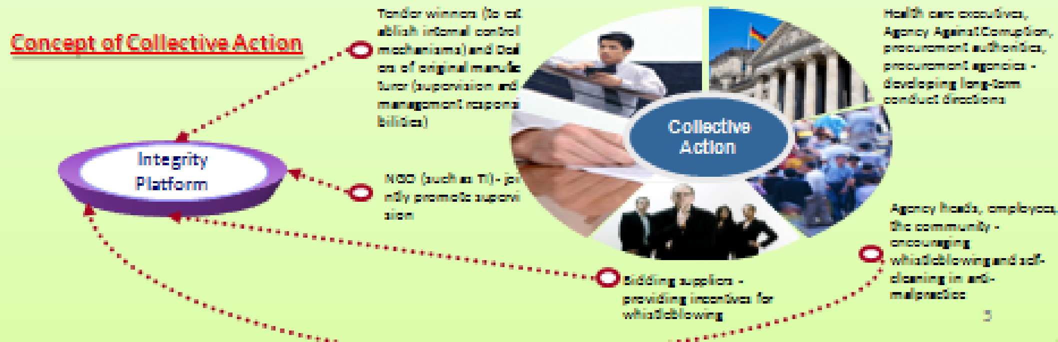
Some Ethics Criteria Do Exist in Chinese Taipei

- "Ethics Code for Medical Doctors" adopted by Physicians Association in 1999.
- The "Governing Principles for Medical Doctors and Manufacturers of medicines and Medical Equipment" prescribed by then-Department of Health in 2006.
- The "Integrity and Ethics Directions for Civil Servants " approved by the Executive Yuan in 2008.
- The "IRPMA Code of Marketing Practices" In 2010.

4

Medical Ethics Platform

- The Ministry of Health and Welfare of Chinese Taipei on February 7, 2013 called a meeting to discuss the establishment of a medical ethics platform.
- No separate standards will be enforced but special chapters will be added to regulate the conflict of interests between the two industries.



Agency Against Corruption

- As the competent branch of the government for this matter, AAC will passionately participate in the creation of the medical ethics code.
- It is hoped the code will not only serve as a declaration of determination but also provide the standards for observance by all stakeholders.

Thank You For Your Attention
http://www.aac.moj.tw
Agency Against Corruption, Ministry of Justice

APEC Healthcare Stakeholders Awareness High-Level Meeting: Fostering Ethical Environments in the Medical Device & Biopharmaceutical Sectors

Nusa Dua (Bali), Indonesia │3 September 2013

-- BREAKOUT DISCUSSION SUMMARY—

- Recommendations for healthcare professional organizations (physicians, nurses, pharmacists)
  - Add business ethics to medical school curriculum and continuing education programs
  - Encourage adoption of the APEC Kuala Lumpur and Mexico City principles
  - Identify effective methods to enforce the principles within associations and share enforcement best practices among healthcare professional organizations
  - Identify an ethics champion within each healthcare professional organization

- Recommendations for APEC governments
  - Encourage relevant government agencies to serve as vocal advocates for strengthened ethical interactions in the healthcare sector
  - Ensure that all relevant government agencies are engaged
  - Have each relevant agency identify a champion responsible for strengthening ethical interactions with industry and healthcare professionals
  - Include ethics training for civil servants
  - Encourage adoption of the APEC Kuala Lumpur and Mexico City principles

- Recommendations for industry
  - Support the teaching of business ethics in business schools, public service schools, medical schools, and continuing education programs for healthcare professionals
  - Identify an ethics champion within each industry association and company
  - Develop, implement and train on codes of ethics consistent with the Kuala Lumpur and Mexico City principles
  - Identify an ethics champion within each healthcare industry association and company to maintain and promote the codes of ethics consistent with the Kuala Lumpur and Mexico City principles and address emerging ethical issues
  - Recruit media as a long-term partner in promoting ethical interactions in the healthcare sector and consider the use of public awareness campaigns

- Recommendations for APEC
  - Continue to facilitate an open dialogue among all healthcare stakeholders
  - Further explore issue of transparency and disclosure issues (between physicians and industry and between governments/procurement and industry) as well as how transparency can be best achieved (possibly through the creation of an APEC framework or model?)
  - Share model practices across APEC, such as incentives to compliance and disincentives to violators, model regulations, model enforcement mechanisms, training best practices
  - Share/Track progress - Map current practices, develop agreed metrics, and track economies and associations progress with an annual report card. Distribute report widely.
  - Expand KL train-the-trainer model (create change agents) to physicians and public servants (as KL was focused on industry associations). Or create a speaker bureau with a standard toolkit that can conduct trainings in economies.
  - Explore collaboration with organizations like the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and others that may have existing tools that APEC might leverage

APEC Healthcare Stakeholders Awareness High-Level Meeting:

Fostering Ethical Environments in the Medical Device and Biopharmaceutical Sectors

Nusa Dua, Indonesia – 3 September 2013

STATEMENT

With the common goal of building awareness and promoting support for initiatives to foster ethical business practices in the medical device and biopharmaceutical sectors across the 21 Asia Pacific Economic Cooperation (APEC) member economies, we – representatives from healthcare providers and professional organizations, anti-corruption agencies, health ministries, health regulatory agencies, health-related government procurement agencies, biopharmaceutical and medical device associations, and private healthcare companies from across the APEC region – met in Nusa Dua, Indonesia, on 3 September 2013 by joint invitation of the Ministry of Health and Ministry of Cooperatives and SMEs of the Government of Indonesia and by the co-sponsoring economies of the "Business Ethics for APEC SMEs Initiative."

We recognize that ethical collaboration among industry and healthcare providers and governments promotes broad patient access to life-saving and health-enhancing medical technologies and therapies that are safe, effective and of high quality. Further, we recognize that ethical collaboration is essential to the development of new innovative medical technologies and therapies that meet patient needs. We continued our dialogue about how we can work closely together to strengthen ethical business practices in the healthcare sector.

We affirmed the statements made by APEC Leaders in 2012 that corruption is "...a tremendous barrier to economic growth, the safety of citizens, and to the strengthening of economic and investment cooperation among APEC economies" and that: "we recognize the important role of business and public-private partnerships in promoting the elaborating of codes of conduct in the private sector and measures to fight corruption, especially measure that support the promoting of ethical business practices in interactions between government, business and other stakeholders."

We also affirmed our support for The Kuala Lumpur Principles for Voluntary Codes of Ethics in the Medical Device Sector as well as The Mexico City Principles for Voluntary Codes of Ethics in the Biopharmaceutical Sector. We acknowledged APEC and its SME Working Group for its leadership in convening expert working groups composed of industry, government and civil society to develop these high standard principles and for providing initial capacity building funds to begin to have them implemented.

We agreed that the creation and endorsement of The Kuala Lumpur Principles and The Mexico City Principles ("the APEC principles") was an important first step toward promoting sustainable economic growth in the medical sector. We also agreed that as leaders of healthcare provider and professional organizations, senior health regulators and health ministry officials, anti-corruption officials, health products and services procurement agencies, and industry we have a responsibility to take further steps together to promote an ethical health care environment in our economies and in the APEC region. We

noted that this work is fundamental to APEC's core mission of promoting economic cooperation because healthy populations are the foundation of sustainable economic growth and health care products and services account for a growing share of international trade and economic activity as economies develop and as populations age.

We therefore established that each stakeholder has a unique and important role to promote ethical health care environments:

Healthcare Companies should follow high ethical standards, such as the APEC principles, as well as all applicable laws and regulations, as part of their mission to help patients by developing and making life-saving and health-enhancing medical technologies and therapies available.

Healthcare Providers and Professional Organizations have a duty to act in the best interests of patients and recognize the importance of their role in communicating the importance of interactions based on ethical principles, such as the APEC principles, including through complementary activities and ongoing dialogue with all stakeholders.

Health Ministries and Health Regulatory Agencies should recognize the value of industry codes of ethics and encourage all stakeholders to support ethical principles, such as the APEC principles, and national and local industry codes of ethics.

Government and Private Procurement Entities should procure health products and services based on transparent, ethical, clear, and accountable policies, processes and procedures.

Anti-corruption Authorities should objectively apply clear laws, welcome industry self regulation as complementary to law enforcement, and encourage all companies to adopt and adhere to uniform ethical principles, such as the APEC principles, and national and local industry codes of ethics.

We agreed that sustained capacity building, dialogue, and high level support are crucial to ensuring continued progress.

We therefore called on APEC to institutionalize the "Business Ethics for APEC SMEs Initiative" by creating an ongoing, high-level "APEC Business Ethics Forum" to foster regional cooperation through multiple avenues, including capacity building, best practice sharing, and multi-stakeholder dialogue to address new and emerging business ethics challenges and the role of all stakeholders in strengthening ethical business practices. Such a forum would foster an external business environment and internal company environment that will permit SMEs to operate on a sustainable basis and serve as global suppliers. Ethical collaborations will also promote patient access to life-saving and health-enhancing medical technologies and therapies, as well as support the development of new innovative medical technologies and therapies.

Background

The Asia-Pacific Economic Cooperation (APEC) forum is the region's premier economic forum, leading numerous initiatives that facilitate economic growth, cooperation, trade and investment in the Asia-Pacific region and among its 21 member economies. Launched in 2010, the "Business Ethics for APEC SMEs" initiative has championed the creation of APEC principles for voluntary codes of business

ethics in several sectors of significant importance to SMEs in the region, including the medical device and biopharmaceutical sectors. Heightened ethical interactions in these healthcare sectors are crucial to enhancing patient access to safe and effective medical technologies and therapies, promoting SME innovation, building SME export confidence, and ultimately ensuring that decisions are made in the best interest of patients.

Drafted and finalized by expert working groups in 2011 and endorsed by APEC Leaders, APEC Ministers, and APEC SME Ministers The Kuala Lumpur Principles for Voluntary Codes of Ethics in the Medical Device Sector and The Mexico City Principles for Voluntary Codes of Ethics in the Biopharmaceutical Sector call upon all stakeholders, including governments and healthcare professional organizations, to coordinate with their local industries to advance ethical collaborations consistent with their provisions. In 2012, APEC Leaders called for collaborations to propagate codes of ethics aligned with these APEC principles to promote ethical interactions between government, business, and other stakeholders.