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GOOD PHARMACY PRACTICE IN COMMUNITY AND HOSPITAL SETTINGS
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世界藥學會之參考指南
優良藥事執業規範 _ 在社區與醫院的環境
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前 言

在最近幾年，這「藥事照護」[1] (1) 名詞已被認知為執業的哲學理念，經由藥師的專業服務讓病人與社區為最主要的受益人。這概念尤其對下列特殊群體如老年人、母親與小孩、慢性病人，以及對整體社區民眾而言，有節省成本的意義。由於藥事照護的基本概念與優良藥事執業(Good Pharmacy Practice, GPP)大部分相同，可以說優良藥事執業是執行藥事照護的一個舞台。

當要為GPP發展品質保證系統時，各國之間的重要差異必須考慮進來。各國都應以長期藥事執業的眼光來做規劃，因此，策略規劃的第一步就要決定什麼是病人、醫師、政策決定者、健保局及其他醫療團隊所期望的藥師功能？[2] 然後確定誰要為那些功能負起責任。各國家也要描述藥學專業能在醫療照顧鏈中帶來哪些重要的貢獻與勝任能力(key competencies)，包括在醫療照顧的各個執業環境。

因此，這篇參考指南是要用當今的執業標準及思考來定義優良藥事執業，同時要強調出GPP能提供一套系統，其中藥師能提供藥事照護。藥師是以病人為中心，經由藥事照護讓病人能適當地使用藥品而得到更好的治療。

最後，這文件也期望能鼓勵該國家的政策決定者，能焦點關心到藥師在社區與醫院藥局的工作環境，建立GPP規範來引導藥師的執業。由於各國的執業環境差異很大，各國藥學組織(學會、公會)應自行決定能達到何目標，以及何時能達到。

此文件所包含的資訊是反映2008~2009年所做前導性研究的結果，以及FIP的GPP工作小組所收集與討論的資訊。一些文字內容是採自FIP/WHO guidelines on GPP in the community and hospital settings，加上網路上收集與FIP會員國藥學組織所提供的研究文獻。

[1] 藥事照護(Pharmaceutical care) 是一個以病人為中心的執業，藥師願意負起責任來滿足病人對藥物相關的需求，並對該承諾負起成效責任。(1)

[2] 藥師是醫療照顧的專業人員，其專業職責包括確保民眾所接受的藥物治療能得到最大的治療效益。這需要藥師們持續吸取藥事執業與藥物科學的發展新知，專業執業標準的要求，醫藥執業的法規，以及藥物與科技使用的最新知識。(41)

Box reference 1: GPP指南的發展歷史

在1986年第39屆World Health Assembly採用WHO修正的用藥策略後，WHO 舉辦了兩個會議來探討藥師的角色 – 於1988年在New Delhi (2) 以及1993年在Tokyo (3)。之後，於1994年五月第47屆World Health Assembly制定WHA47.12，決議"藥師的角色在支持WHO修正的用藥策略"。

後來，WHO又舉辦兩場會議來探討藥師的角色 –1997年在Vancouver (5) 以及 1998年在The Hague (6)。這些會議強調需要做藥學教育課程的改革，以及藥師在病人自我照顧與自我給藥上的附加價值。

在1992年，the International Pharmaceutical Federation (FIP) 在"Good pharmacy practice in community and hospital pharmacy settings"標題下發展了藥局服務的標準(standards)。於1994年優良藥事執業的文章被送到11月28日到12月2日在日內瓦舉行的WHO Expert Committee on Specifications for Pharmaceutical Preparations會議中。於1997年在WHO Expert Committee建議之下以及FIP Council的背書之下，在1999年 FIP/WHO 共同出版 Good Pharmacy Practice，文件登載於thirtieth fifth report, WHO technical report series No.885。(7) (8)

於2006年，在與WHO合作下，第一版實用的手冊“Developing Pharmacy Practice – A Focus on Patient Care” (9) 正式出版。這手冊的設計在滿足對藥師需求的改變，規劃出一個新的藥事執業領域，並呈現出執行藥事照護的個別步驟。

為了總目標能夠改善藥物傳送與使用的標準與執業，使用 FIP/WHO Guidelines for Good Pharmacy Practice (GPP) 當作架構，FIP 於2005~2007年也以前導性研究方式，嘗試提供技術性的協助其會員國組織，如在Thailand, Uruguay, Vietnam, Moldova, Mongolia, Paraguay and Cambodia 以發展GPP的國家標準。(10)

於2007年, 在東南亞區域的“Bangkok declaration on good pharmacy practice in the community pharmacy settings” (11)被 FIP South East Asia Pharmaceutical Forum 所接受，並設定承諾為其區域的會員國藥學組織提升藥學專業服務的標準。

自1993年開始，藥事執業、應用科學與科技以及藥學政策有非常顯著的改變，包括

WHO resolutions, WHA54.11 (WHO Medicines Strategy), WHA54.13 (Strengthening health systems in developing countries), WHA55.14 (Ensuring accessibility of essential medicines), WHA55.18 (Quality of care: Patient safety), WHA57.16 (Health promotion), and WHA60.16 (Rational use of medicines)。因此，一個更新的 FIP/WHO joint Good Pharmacy Practice 文件是需要的，以反映當前的執業標準與想法。

於 2008 年，FIP 的 GPP 工作小組在 Basel 舉辦了一個專家諮詢會議。此會議的報告確認了幾個重要議題，在更新 GPP 指南時必須要清楚考慮。(12) (請看附錄 2)。

Box reference 2: 東南亞區域 GPP 政策與計畫的優先檢討方向

第一個區域性GPP政策與計畫的會議是由SEARPharm Forum所舉辦，在FIP Foundation, WHO-SEARO, WR Thailand, Thai FDA and the Thailand Pharmaceutical Association支持下開始討論GPP發展、在東南亞區域國家的政策與計畫，並以泰國為計畫執行的國家。一些西太平洋藥事論壇(WPPF)區域的國家也受邀來分享經驗。此會議的目標是要提升在該區域的GPP發展，因為GPP可以提升藥事服務的標準，同時增進專業服務的態度與藥師行為，以改善社區民眾的健康。

在會議結束時，下列六項優先檢討事項被確定出來：

1. 在藥學專業內先要改變對藥師角色的認知
2. 改善藥事執業的品質
3. 記錄下來並宣導出去藥師在醫療供應鏈中，對社會以及病人所帶來的價值與利益
4. 提昇民眾對藥師/藥局角色在附加價值上的認知
5. 藥學組織與區域性藥事論壇的角色
6. 藥師養成教育與持續教育

於 2008 年 8 月在 Indonesia 舉辦的第二次區域性會議上，有討論各國家的進展，並焦點集中在發展品質管理與執行計畫。

致謝詞

這一本優良藥事執業規範的參考指南是由 International Pharmaceutical Federation (FIP) 的Board of Pharmaceutical Practice (BPP) 所啟動，來支持更新1993年的 FIP/WHO Statement on Good Pharmacy Practice。最主要的BPP工作小組成員是 Henri Manasse (co-chair), Dick Tromp (co-chair), Lowell Anderson, Colin Hitchings, Eeva Teerasälmi, Raj Vaidya, Jacqueline Surugue, Frans van der Vaart and Marthe Everard (WHO)代表社區/醫院藥局及醫療系統服務的專家。而總管理的工作是由FIP的 Xuanhao Chan and Ton Hoek 所支持。

此處也要感謝下列人員的貢獻：

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Special appreciation goes to the staff of the 37 FIP Member Organisations who contributed information on their national GPP standards and other authors whose work has been documented in this publication.

本文章是由譚延輝博士於 2010 年二~七月所翻譯，譚執行長服務於中華民國藥師公會全國聯合會，藥事照護發展中心。

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簡 介

優良藥事執業規範(Good Pharmacy Practice, GPP)是藥學專業的心臟，更是專業執業的精華與本質。它代表藥師與病人之間的互信關係，不只是用藥'不受到傷害'更是協助用藥達到理想的治療效果。

閱讀這本參考指南的主要對象是服務於藥學專業兩個領域的藥師：社區與醫院藥局，他們都在直接照顧病人。當專業執業持續進展，這兩領域藥師的服務內涵愈來愈難清楚區別，因為病人照顧已走向整合性服務，要努力達成無縫隙的連續性照顧。因此，這份文件所談的原則適用於兩處執業的藥師。

藥事執業在各個國家、各個區域都有很大的差異，這份文件有將這些差異性考量進去，因此彈性很大。藥學專業目前以快速步伐進展中，藥師的新角色不斷被提出與宣傳出去，這不單是藥學界在宣傳，其他醫療專業以及國家或國際藥政法規機構也都在要求。這份文件想要有充分彈性以因應未來有相關新角色的出現。

此處要強調這份文件僅在提供一份參考資訊，是為FIP的會員組織(各國家藥學會、公會)以及其國家藥政組織和其他相關團體，為規劃GPP文件及相關法規所參考。這文件不是用來建立執業標準，也不是提供一個模板來製作GPP文件。

藥學專業的考量與態度在整份文件中一直被強調，而病人的福祉與安康是最優先的重要考量因素。然而可以看到經濟因素也是常被提到，這是對的，也是適當的，因為全世界都在探討藥費太高或藥品使用太多的議題，提供照顧的收費議題，以及應用醫療照顧新科技於現代執業的議題。許多適當發表的研究文獻與基於國家藥學團體經驗所提出的執業建議，也會在此文件中分享。

這本參考指南可看成是先驅者，讓FIP創造出政策文件，這也是1991年GPP政策聲明的更新版本。

哲學理念

挑戰著各國政府與醫療照顧領導者的重大議題，包括方便與及時獲得照顧，病人安全及獲得良好治療結果，有充分與穩定財務資源，以及各醫療照顧專業人員的執業範圍。藥師，一位用藥的專家，在討論與解決這些議題上有很重要的角色可扮演。(13)

一個藥學專業團體必須思考一個讓自己成功的使命，即成為推展藥學專業發展的統一驅動力。從一開始的訓練一直到退休，甚至退休後，他必須支持教

育、創新、最好的執業以及專業成長；他必須支持藥學內通科(generalists)與專科藥師(specialists)的建立與發展，並讓其會員都能達到專業執業目標。(14)

藥事執業的使命是提供藥品與其他健康照護產品，一致的專業服務，以協助民眾及整個社會能最佳的使用藥品。

藥師的執業傳統上被認為是保管藥品、準備與調劑藥品，再配合管理系統與資訊來確保有品質的使用藥品。藥師運用藥品的專業知識及治療來達到最適當的治療結果。(15) 一個完整的藥學服務應包括許多藥師的行為，能確保社會群體獲得好的健康並預防傷害產生。一個藥局應照顧病人的健康，公共的衛生與環境的保護。當病人的一個疾病或傷害接受藥物治療時，藥師應確保在藥品使用過程中的品質，以達到最佳的治療效益並避免副作用產生。

藥事執業應該要管理病人照護並確保達到適當的藥物治療結果。健康促進以及疾病預防都是藥事執業及有效藥物治療管理重要的一環。藥師，做為一位訓練精良的藥品管理專家，具有領導的角色，必須與其他醫療專業人員合作，針對複雜的藥物治療，協助病人更理想的管理其疾病。(16)

藥師應從櫃台後面走出，開始對大眾提供藥事照護而不是僅提供藥品。藥師僅僅販賣藥品是沒有前途的，因為將會被網路、機器或技術員所取代。事實上，藥師有養成教育、具有專業證照，做為醫療照護人員一份子，應做的比現在角色要更好，來服務與照顧民眾的安全與健康。(17)

由於世界各地的社會經濟狀況差異很大，可能導致病人照顧無法做得很好。在這些國家或地區，藥師的執業可能會以產品為導向，而不是以病人為中心。但需要強調的是，雖然有這些經濟上的挑戰，各國家藥學組織以及其政府必須規劃出步驟，以最大努力來確保藥師能以病人為最優先考量，而不管外界社會的壓力。

Box reference 3: 臨床藥學服務的經濟衝擊_一個文獻回顧 (18) (19) (20) (21)

依據2008年六月15日美國ASHP的一個回顧性文章，臨床藥師在醫院住院病人環境的介入可改善病人療效並減少及避免醫療花費。

在回顧1996到2007年之間發表的21篇研究文章，臨床藥師在財務方面的價值有很顯著績效，因為他們參與節省成本的介入活動，如停止不需要的藥物治療，改變使用較便宜的藥物治療等。回顧的作者同時發現藥師若參與醫師查房，藥品花費也有降低。因為查房前藥師會收集病人資訊，評估病人治療效果，而在查房時提出改變藥物治療的建議。

藥師同時可避免藥品不良反應的發生而節省醫療花費，更合理使用抗生素而降低成本。其他較廣泛的臨床服務如回顧病歷與用藥歷史也可降低醫療成本。

所回顧之文獻顯示出醫療成本節省大約在一個24週的期間節省美金$1,977元(外插法計算約一年節省$9,135美元)；到22天內節省$251,764美元(外插法計算約一年節省$4.3佰萬美元)。這些節省大約是一天$12 to $11,444 美元。

這些作者建議未來的臨床藥學經濟研究應該有比較性的研究設計，如執行臨床介入之前與之後的比較。未來研究也應該包括從社會立場分析的"遞增成本效果數值或成本利益比值(incremental cost-effectiveness or cost: benefit ratio)來呈現"。

Further reading:

1. *The Iowa Continuity of Care study: Background and methods.* Barry L. Carter, Karen B. Farris, Paul W. Abramowitz, David B. Weetman, Peter J. Kaboli, Jeff rey D. Dawson, Paul A. James, Alan J. Christensen, and John M. Brooks. 2008, Am J Health-Syst Pharm, Vol. 65, pp. 1631-46.
2. *Pharmacist-led program to improve venous thromboembolism prophylaxis in a community hospital.* Jered B. Bauer, David S. Chun, and Todd A. Karpinski. 2008, Am J Health-Syst Pharm, Vol. 65, pp. 1643-7.

Box reference 4: 社區藥局對改善民眾健康的貢獻 (22) (23)

這篇報告呈現一個摘要總結的發現，引用的證據來自於一篇發表在有同儕審查雜誌的回顧性文章，這是從2004到2007年間社區藥局貢獻於改善公眾健康的證據整理。這近期的回顧加入更多證據到原先兩個時期的證據1990-2001及2001-2004。這是衛生署所委託的計畫，摘要列出的證據重點在治療效果、品質、成本/成本效益及綜合技能。與藥師相關的態度與執業實證發現也有摘要呈現。

結論

這回顧發現有顯著多的研究顯示以社區藥局為基地的服務，如戒菸、心血管疾病管理與預防、糖尿病篩檢與管理、高血壓都有顯著的效果。由於許多研究的地點不是在英國，與英國的執業環境不同，因此還需要更多在英國執行的研究來證明。有一些效果的證據是用於骨質疏鬆的風險評估及體重管理，這些領域都顯示很有未來性，值得以前導性測試方式做進一步研究。

早期研究(24) (25)的回顧結果，一般顯現藥師在貢獻於提昇民眾健康方面有正面的趨勢，但藥師目前工作環境的約束作用、目前的薪水酬勞安排方面及一些社區藥局經營的前提等，也都有描述。教育訓練顯然是改變社區藥師執業的重要因素，才能執行提升健康的活動，並需要學習更整體的執行步驟。研究顯示藥師目前較安心於執行與藥物使用有關連的改善健康活動。另外，文獻顯示，目前藥師多採用回應式(reactive)而不是前瞻性(proactive)的態度照顧病人。

Further reading:

The contribution of community pharmacy to improving the public's health: Evidence from the peer-reviewed literature of 1990-2001. Anderson, C, Blenkinsopp, A, and Armstrong, M. 2003, PharmacyHealthLink and Royal Pharmaceutical Society of Great Britain.

The contribution of community pharmacy to improving the public's health. Evidence from the peer reviewed literature 2001-2004. Anderson C, Blenkinsopp A, Armstrong M. 2005, PharmacyHealthLink and Royal Pharmaceutical Society of Great Britain.

Libby Roughead, Susan Semple, Agnes Vitry. *The value of the pharmacist in the community: a systematic review of the literature 1990-2002.* University of South Australia, Quality use of medicines and pharmacy research centre

Box reference 5: 在撒哈拉沙漠以南的非洲地區(SSA)改善藥事照護模式對人力資源的挑戰以及HIV/AIDS的全國流行情形 (26)

總結摘要:

藥事照護，用意在輔助一個適當的藥品供應系統，是一個強固健康照護系統的重要組成之一，是直接負起責任來提供藥物相關的照顧，用來達到期望的藥物治療目標進而提昇病人的生活品質。在單純調劑藥品之後，藥事照護能提高服藥的配合度，並發現/解決及預防藥物治療的問題，如劑量過高、過低，藥物不良反應，治療禁忌及不符合適應症。Sub-Saharan Africa (SSA)地區缺乏有經過藥事照護訓練的醫療人員，同時缺乏藥品，這造成多重疾病管理的挑戰(有全世界25%的疾病負擔但只有全世界1.3%的醫療人力)。為避免及治療HIV/AIDS, TB, malaria及其他疾病，最緊急需要的是訓練與整合目前在處理重要與輕微疾病藥品問題的工作人員，尤其是在有執照藥局或藥房的工作人員。在SSA區域內的大多數國家，藥事照護還在發展初期，但需要成長並符合該國家的需要來成長。SSA的解決方案需要建立健康照護系統的各個部門，其中有幹部可執行藥事照護同時也做藥品的儲存與調劑工作。在執業前的教育課程修訂、更多在職人員的繼續教育以及訓練藥師來督導藥師助理等等，是目前發展藥事照護最主要的部份。

重要傳達訊息

此文章指出並討論目前在SSA地區應用目前環境去發展藥事照護，最緊急需要的事項包括：訓練中心數量不夠，腦力資源缺乏，每單位人口的藥師數量太低，在偏遠地區與都會區的藥師分配不平均，藥事技術員或助理的訓練不夠且數量缺乏，藥物法規部門的資源缺乏，廣泛使用偽藥與劣藥，以及由未訓練或訓練不夠的醫療工作人員或他人來處理藥品。SSA地區國家要發展藥事照護必須要有轉變：在執業前教育課程內加入藥事照護課程，發展訓練課程或模式去教育護理及醫學院學生，對藥師、護理師及醫師作繼續教育談藥事照護，發展策略到各國家去再教育工作人員，以及最需要的是訓練並正式化藥事技術員或藥師助理的存在位階。

因此，SSA的解決方案需要再細調藥師的傳統執業角色。這研究進一步建議一個新的模式來提供藥師照護，這牽涉到四個層面：藥師，調劑醫師，護理師及藥事技術員或藥師助理。

Further reading:

The 2009 FIP Global Pharmacy Workforce Report. Available online at http://www.fip.org/hr (27)

"The global pharmacy workforce: a systematic review of the literature". (28) The article aims to explore contemporary issues surrounding expansion of the global pharmacy workforce. The journal is open access and the article can be downloaded at: http://www.human-resources-health.com/content/7/1/48.

Box reference 6: 藥師為病人健康與偽藥作戰

有許多報導呈現出低於標準的偽劣藥物製劑在國際貿易上有廣大的普及性。發展中國家最常暴露於這類產品，而造成無效或毒性反應並威脅著民眾對醫療照顧系統的信心。就是這個原因1994年5月的47屆World Health Assembly決議採用WHA47.12對藥師角色的解決方案，要求藥師應有責任確保他們所調劑藥品的品質。這解決方案同時認同藥師在公共衛生上有重要角色，尤其在合理藥品使用上，必須在任何時間所有人民能得到優良品質的必須藥品(essential drugs)，同時其價格大家都付得起(4)。病人及醫療提供者必須確保他們是從合法的處所買到藥品，如藥局，及有適當訓練的人，如藥師。

富裕的國家通常有依據法律建立的良好藥物法規系統。這可經由下列幾種機制來監測與確保製藥工業所生產藥品的品質：法規部門發出藥品上市許可證，對製藥廠的查核與GMP認證，大盤商與其他經銷商，社區與醫院藥局，政府實驗室的品質控制抽檢。許多發展中國家缺乏有效的藥物法規系統，他們將藥物製劑品質的主要責任與負責情形都歸給藥師。然後他們必須依賴自己或他們的藥學組織來做品質評估，來確認他們所購買之藥品來自於有信用的來源。FIP已針對藥品採購發展出特定的指引。(29)

我們應該知道藥品的特質是要治療病人的疾病，而偽藥將為害病人的安全。為維持長期的安全性，合法的製藥工業產銷鏈必須再強化其結構，以保障全世界合法藥品銷售管道的安全。

製藥工業產銷鏈的所有利害關係人應盡力保障供應鏈的完整性。(30)有必要考慮藥品及衛材的追蹤性，即從生產製劑到用在病人身上。因此，藥師在供應鏈的每一步驟都應有更強的角色，來減少偽藥的危害與增進病人安全。

Further reading:

1. *FIP's framework for establishing a national guide for pharmacists in combating counterfeit medicines.* International Pharmaceutical Federation (FIP) 2009, The Hague
2. *Trading in False Hopes: A review of medicines counterfiting as a world-wide threat and the need for strengthened international collaboration to reduce pharmaceutical crime and promote global health.* Taylor D and Craig T. 2009, The School of Pharmacy, University of London

優良藥事執業之定義

優良藥事執業(Good Pharmacy Practice, GPP) 是一種藥事執業，針對病人的需求，藥師提供實證為基礎的最佳照顧。為支持這種執業，有必要建立國家的品質標準與指引架構。

優良藥事執業之執行需求

1. 優良藥事執業需要在各地執業的藥師，都能以病人的福利為最優先考量。
2. 能提供藥品與確保藥品適當使用之所有流程，都考量到病人健康、公共衛生與環境保護。
3. 藥局活動的核心是藥品與其他醫療產品的提供，都能確保品質、適當地資訊與用藥指導以及監測使用後的效果。
4. 藥師最重要的貢獻在鼓勵安全、合理、經濟及有效的藥物治療。
5. 藥師服務的每一項功能都與病人有關，有清楚定義，並與所有相關人員都有充分的有效溝通。
6. 需要團隊合作來達到成功的藥物治療管理，包括藥師、醫師、護理師以及其他醫療照顧相關人員。

7. 需要病人能容易接觸到藥師，而藥師能提供基層醫療所需的教育與指導，以提升健康並降低疾病的發生率。(15)

為達到這些需求，應考量下列狀況：

1. 執業最重要的理念就是專業性(Professionalism)，雖然經濟因素也很重要。
2. 藥師應對藥品使用的決定發揮主動精神。應有系統建立能讓藥師通報藥品不良反應，用藥疏失，藥品製劑品質不良或發現到偽藥。這個通報內應提供藥品使用的資訊，不論藥品是從醫師、藥師或自購的來源。
3. 與其他醫療人員的關係，尤其是醫師，應視為治療夥伴關係，而能在所有藥物治療相關構面上建立互信與保密的情誼。藥師應建立專業判斷的自主權。
4. 藥師與藥師之間的關係應為同僚(colleagues)，一起尋求增進藥學的服務，而不是競爭者的關係。
5. 所有藥師必須為定義、評估與改善他們專業執業的品質，接受一個共同分擔的責任並對其結果負責。
6. 藥師應要能接觸到每一病人的必須(essential)醫療與用藥的資訊。
7. 病人若只選擇到一家社區藥局調劑，則病人與藥師的關係可強化許多。藥師需要獨立、完整、客觀與最新的病人正在接受之治療與用藥資訊。
8. 在每一執業處所之藥師應在專業執業的生涯中，接受自己有責任，對維持及評估自己勝任能力(competence)的結果負責。
9. 藥師應認知到藥品對自然環境的影響是事實，當處理藥品廢棄物時，必須永遠想到該如何減小這些衝擊的可能性。
10. 對藥局管理者而言，他們必須決定與確保支持人員(support staff)在執行各類藥事作業時，所需要的勝任能力與負責任的程度(levels)，這些支持人員可能是藥事技術員或藥局內的助理。
11. 藥學院系的藥師培育課程應適當地強調目前與可預見之未來，在藥事執業上的變化。
12. 優良藥事執業的國家標準必須明確制定且要求所有執業藥師來遵守。

Box reference 7: 美國醫療系統藥師學會 (ASHP) – 藥師之使命 (32)

藥師將會：

1. 執行領導功能，經由改善病人的藥品使用與整體藥品使用流程，而顯著提升病人的健康相關生活品質。
2. 管理病人藥物治療並提供病人相關的照顧與公共衛生服務。
3. 成為主要的人員負責藥物使用與藥品發送系統。
4. 被認定為醫療照顧提供者，並被病人認定可以協助他們達到最理想的治療結果。
5. 承擔領導角色來持續增進並重新設計藥品使用流程，其目的在顯著提升(a)病人安全，(b)醫療效果，(c)合理使用人力與醫療資源，(d)效率。
6. 引導實證藥品使用計畫以執行最好的執業。
7. 在病人、醫療專業人員、醫院行政長官及公共衛生政策決定者的心目中，認定為有熱誠、願關懷病人的藥品使用專家。

Box reference 8: 為達到藥學使命加拿大藥師學會所採納之重要指導原則 – 藥學的藍圖 (13)

1) 藥師及藥師助理以他們的知識與技能做最大程度的執業，並整合到最新發展的醫療照顧模式中。
2) 藥師及藥師助理運用助理增加的角色及調劑自動化系統，來保護藥品發送系統的用藥安全性、工作環境安全性(security)與完整性。
3) 藥師及藥師助理引導藥品使用安全及品質提升的發展及參與組織活動。
4) 藥師與病人、其照顧者以及其他醫療提供者合作，共同管理病人的藥物治療。
5) 藥師確認出藥物使用的議題，負責藥物治療的決定並監測病人療效結果。
6) 藥師開處方、修改及維持藥物治療(如:經由跨專業合作之協議書或醫院核定之指示)以及開生化檢驗單。
7) 藥師與病人共同參與治療之決定，並積極協助病人執行健康提升、疾病預防及慢性病管理的活動。
8) 藥師進行執業的研究，參與實證依據的醫療照顧政策與制定病人照顧的最佳執業指引。

Box reference 9: 社區藥局與醫院藥局執業的獨特領域	
社區藥局	**醫院藥局**
✓ Direct patient contact – some long term, some very short term ✓ Compliance and consistent use of medicines ✓ Self care ✓ Cognition / literacy of patient ✓ Product and service aspect packaged together ✓ Customer services ✓ Contact with internet patients ✓ Contact with patients through a third party ✓ Extemporaneous preparation ✓ Health information in the community ✓ Isolation as a professional, not part of a team ✓ Lack of clinical patient information ✓ External influences affecting practice ✓ Cost issues impinging on professional matters ✓ Confidentiality issues ✓ Medication reconciliation/comprehensive medication record (community/hospital/nursing home) ✓ Health promotion ✓ Legal framework within which to work ✓ Home delivery of medicines ✓ Home visits by pharmacists ✓ Medical supplies/oxygen/renal dialysis ✓ Contact with drug addicts ✓ Screening for diseases eg. diabetes/BP/cholesterol	✓ Parenteral Solutions, IV admixtures ✓ 'Bedside' clinical care, ward rounds ✓ Hospital Formulary ✓ Drugs & Therapeutics Committee ✓ Medical Gases ✓ Manufacturing ✓ TPN ✓ Satellite Pharmacies ✓ Emergency/life threatening situations ✓ Complex therapy ✓ Rapid turnover of patients ✓ Clinical trials and investigative drugs/work ✓ Cytotoxics ✓ Radiopharmaceuticals and diagnostics ✓ Medical devices and IV pumps ✓ Sterile materials, handling distribution and preparation ✓ Complexity of the organisation ✓ Infections ✓ Individualised medicines ✓ Access to laboratory data and biomarkers ✓ Procurement – through tenders ✓ Specialized softwares – informatics, Drug Information Centre ✓ Proteomics, Genomics and other "omics", gene therapy ✓ Biochips, biosensors and MEMS (micro electro mechanical systems) ✓ Poisoning/intoxication

優良藥事執業規範之應用

社會上藥師服務的對象是誰？

我們的"顧客"可能包括病人、護士、醫師、藥師的雇主、學校老師、政府官員、健保局長官、製藥廠或藥商公司同仁。

若這些人是我們的"顧客"，他們對我們的期望是什麼?

顧客對藥師的期望，可以分為下列幾類共同點(16)：

- 病人可得到適當的藥物治療結果。
- 藥物治療問題可以被發現、解決及預防發生。
- 照顧是可以被協調整合的，執業者有充分的勝任能力。
- 病人所接受照顧是有價值意義的，而且收費是能付得起的。
- 這系統是容易接近的，且以病人最大利益為主要考量。
- 病人與執業者之間有一個專業的互信合作關係存在。
- 這系統能針對適當的藥物使用，提供足夠與適當的資訊與教育。

藥師至少有三種途徑可以定義他們的角色或功能：

1. 藥品管理途徑(請看Box reference 10) – 藥師的功能與藥品如何使用以及藥師如何改善用藥與病人安全的行為，有密切的關係。
2. 以病人為中心(請看Box reference 11) –藥師的功能依醫療系統內一位病人照顧的流程，做一系列組織化描述。
3. 以藥師為中心(請看Box reference 12 and 13) –藥師的功能可從第一天執業開始所需要的全方位知識、技能、態度及價值觀來做描述。

藥師應以"建立一個以病人為中心的藥物使用系統來改善照顧品質"當作目標，來當作藥事執業架構的最基本原則。

以勝任能力為基礎來制定藥事執業標準 (Competency based approaches to setting pharmacy practice standards)

藥師在醫療系統與公共衛生體系下，其角色已愈來愈複雜與多樣化，我們必須強調維持藥師勝任能力的重要性，以擔任一個醫療專業人員所必須有的相關且最新知識、技能與專長(33)。國家層級的各類藥學組織需要與政府相關單位團結工作在一起，來支持國內藥師的發展，經由提供專業持續成長(各類持續教育)以及建立一個國家層級的藥事服務勝任能力架構，其中定義出最基本的藥事服務與執業目標的國家標準。

藥事執業架構的特質 (Characteristics of a pharmacy practice framework)

1. 提供一份藥事執業所有領域的總論。
2. 呈現出最基本的標準並建立目標。
3. 目標不要指定執業處所或特定疾病，但必須能將角色與流程適用於各種執業環境的需求。
4. 目標是達到全面的應用，而重點放在藥物治療管理的基本要素，以及全部病人群的管理，但仍然維持個別病人的照顧。(16)
5. 包括所有藥物使用流程的層面以及提供明確的描述各種需要的成果績效指標。(34)

最近的許多研究指出藥學專業缺乏整體架構，來分辨出不同層次的藥事執業；當前存在的大多數藥師勝任能力架構只適用於特定領域的工作，如小兒科或癌症治療。在英國，目前許多研究正從多領域積極發展與確效一套通用的基本與進階層次的藥事執業勝任能力架構。(35) 要知道更多藥師勝任能力架構的資訊與例子，請參考Box References 10 to 14 以及附錄 1 的37個FIP會員國之國家GPP標準的背景。

Box reference 10: 藥事相關勝任能力架構的來源表列(主要是英國)。請同時看附錄 1 的 37 個 FIP 會員國之國家 GPP 標準的資訊

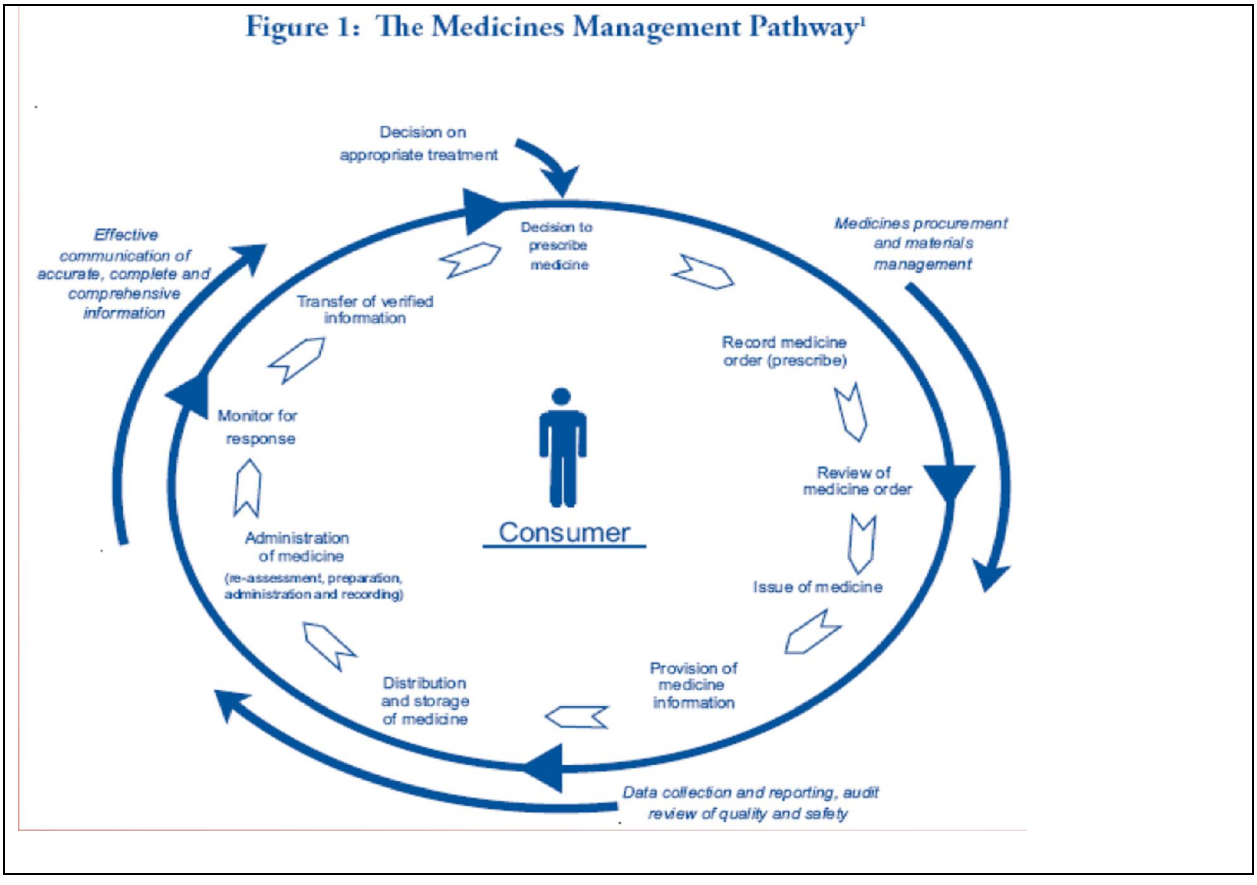
國家	條列藥事勝任能力架構	來源
UK	Competencies for Pharmacists Working in Primary Care, 2nd edition 2003	National Prescribing centre **http://www.npc.co.uk/npc_publications/publicationsdte.htm?type=2008**
	A Competency Framework for Community Health Pharmacy Services, June 2003	Primary & Community care Pharmacy Network **http://www.pccpnetwork.org/publications.asp**
	Maintaining Competency in Prescribing - an outline framework to help pharmacist supplementary prescribing, 2003	National Prescribing centre http://www.npc.co.uk/npc_publications/publicationsdte.htm?type=2003
	General Paediatric Competencies, Sept 2002	College of Pharmacy Practice Faculty of Neonatal and Paediatric Pharmacy www.collpharm.org.uk/FNPCC
	A Competency Framework for Pharmacy Practitioners to Provide Minimum Standard of Pharmaceutical Review: The General Level Framework Handbook 2nd Edition May 2009	Safe Medication Practice Unit Queensland Health http://www.codeg.org/fileadmin/codeg/pdf/SMPU_GLF_Handbook.pdf
	Outline Competencies for Mental Health Pharmacists,2001	College of Mental Health Pharmacists, the UK Psychiatric Pharmacy Group http://www.ukppg.org.uk/cmhp_competencies.htm
	A Competency Framework for Pharmacy Practitioners *General level, 2003, Advanced level, 2003*	London, Eastern & South East Specialist Pharmacy Services, Clinical Pharmacy www.londonpharmacy.nhs.uk/clinical/competency
	Competency Framework for the Assessment of Pharmacists providing the Medicines Use	NHS Community Pharmacy Contractual Framework http://www.wales.nhs.uk/sites3/Documents/498/Ad

	Review (MUR) and Prescription Intervention Service	vancedservicecompetencyframework.pdf
	A Competency Framework for Medicines Information Pharmacists, 2001	United Kingdom Medicines Information (Pharmacists Group) www.ukmi.nhs.uk
	A new professional framework for developing future chief pharmacists, Sept 2008	http://www.pjonline.com/
Canada	Model Standards of Practice for Canadian Pharmacists - April 2003	National association of pharmacy regulatory authorities http://napra.ca/pages/home/default.aspx
New Zealand	The Competence Standards for the pharmacy profession	Pharmacy council of NZ http://www.pharmacycouncil.org.nz/cms_show_download.php?id=38
United States	Academy of Managed Care Pharmacy: Framework of quality drug therapy	http://www.fmcpnet.org/index.cfm?p=132D8447
	Minimum Standard for Home Care Pharmacies	American Health-System Pharmacists http://www.ashp.org/
	Minimum Standard for Pharmaceutical Services in Ambulatory Care	American Health-System Pharmacists http://www.ashp.org/
	Minimum Standard for Pharmacies in Hospitals	American Health-System Pharmacists http://www.ashp.org/
Australia	Competency Standards for Pharmacists in Australia 2003	http://www.psa.org.au/site.php?id=1123
	Professional Practice Standards 2006	http://www.psa.org.au/site.php?id=1094

Box reference 11: 藥物管理途徑 (The Medicines Management Pathway) (36)

藥物管理途徑是在描述使用藥品時的醫療與行為步驟，而重點是以顧客為主。這一共有9個步驟以及3個背景流程。這些步驟與流程都相互依賴，會影響著彼此。將這途徑發展出來可提供一個架構來確認各步驟之間的相連性，以及潛在錯誤與安全系統的改善。這個途徑可應用到所有藥品，不管在任何處所或針對任何醫療專業人員或財務的來源。去瞭解途徑的每一步驟及所牽涉的人員，對確保安全、有效及有效率使用藥品，會有很大的幫忙。這途徑可以協助顧客與醫療專業人員瞭解他們的角色以及他們的行為會如何改善用藥的安全性。醫院藥師早已建立起所有步驟的角色，現在由於社區藥局與其他處所提供的藥事專業服務愈來愈多，這藥物管理途徑的概念，會在各類照顧的連續性上扮有愈來愈重要的角色。藥物療效的追蹤與達到理想用藥療效已是所有藥師的責任。

基於這個概念，澳洲藥學會(Pharmaceutical Society of Australia)在 2006 年建立了 Professional Pharmacy Standards (第三版)。



Box reference 12: 美國AMCP所建立的有品質藥物治療之架構(16)

美國The Academy of Managed Care Pharmacy (AMCP) 在1999年組織了一個工作小組想去設計*Pharmacy's Framework for Drug Therapy Management in the 21st Century*。為完成這目標，發展了一個策略計畫來創立一個模式以執行藥物治療管理(drug therapy management)。這模式可支持一個長久的藥事執業願景。此策略計畫的第一步是確定什麼功能是病人、醫療人員、健保局、政策決定者及教育人員所期望的，並確定出誰應該為該功能負責。這***架構計畫***與以前藥學研究不同之處，是想要聽取更大群體顧客與病人的聲音，來規劃出未來不分執業處所的藥物治療管理。這***架構***廣泛地描述重要的勝任能力，是需要藥師帶到美國醫療照護系統的各個執業處所與環境。它不是想定義出社區藥局內藥師的特定角色與工作內容。

在Grid與自我評估工具內有描述七種核心領域。第一個核心領域是探討一個醫療人員當與病人互動時的應有行為。第二到第七個核心領域是在醫療系統內以一個照顧病人的順序來描述。

US Academy of Managed Care Pharmacy – 藥局服務品質的架構	
1. 採用基本的技能、工作與功能來有效的執行藥物治療管理 1.1 人與人之間的溝通技巧 1.2 病歷留底— 服務的紀錄與維持 1.3 病患教育 1.4 病人安全與工作環境安全 1.5 領導統御 1.6 病人權利與責任 1.7 品質持續增進	5. 有監測病人的藥效，如：效果，服藥配合度，預防副作用，有調整劑量以達到最佳療效。 5.1 病人療效監測與紀錄 5.2 藥物治療調整與改變 5.3 病患教育 5.4 品質持續增進
2. 提供健康管理、健康促進及疾病預防的計畫或服務 2.1 計畫執行的設計 2.2 推廣與可近性 2.3 服務的實際執行 2.4 品質持續增進	6. 有經由一個適當藥物使用政策與利益設計的系統能提供醫療利益 6.1 選擇最佳的治療 6.2 能獲得醫療利益 6.3 病患教育 6.4 藥物使用評估 6.5 品質持續增進
3. 有效的評估病人，有正確的診斷、有選擇適當的藥物治療 3.1 病人病情與療效的評估 3.2 藥品的選擇適當性 3.3 醫師處方藥開列情形 3.4 是否有任何藥物治療問題 3.5 照顧的協調情形 3.6 品質持續增進	7. 醫療系統有執行持續的評估，以確保藥物治療管理的結果能導致健康的個人與群體 7.1 藥物治療評估 7.2 收集與傳播資訊 7.3 品質持續增進
4. 病人給藥系統能以及時方式提供正確藥物治療，提供可理解的健康資訊 4.1 給藥系統安全性與儲存情形 4.2 藥品準備與調劑正確性 4.3 病人給藥紀錄 4.4 病患教育 4.5 照顧的協調情形 4.6 品質持續增進	Note: The “component” tasks, skills and functions in each of the core areas of focus are categorized under “functional areas” of drug therapy management. The components under a given functional area are building blocks that interact to permit the health care practitioner or the system to achieve successful patient care.

Box reference 13: 英國The Royal Pharmaceutical Society of Great Britain執業架構 (RPSGB) (37)

自 2007 年，RPSGB 發展“The Pharmacy Practice Framework”來定義藥師應做什麼、因此需要知道什麼、需要獲得哪些技能以及需要執行的行為。這執業架構不是列出哪些功能，也不是藥師的工作描述，不是一個國家制訂的課程，不是描述高等或專科執業內容，也不是每位藥師第一天上班要做的

事。這是一份聲明，描述一位藥師開始執業的第一天應有的知識、技能、態度及價值觀。http://www.rpsgb.org/pdfs/practiceframework.pdf.

為了捕捉所有各種藥師該做的不同事情變成一個連貫的整體，我們將這些分成下列之描述：

角色(Roles) – 七個相關功能的廣泛角色

功能(Functions) – 一個較細節的描述哪些功能組成該角色(每個角色約有2~6個功能)

活動(Activities) – 真正藥師所做的工作內容(每個功能約有2~5個活動）。每一個活動也有一些指標來反映執業好壞，能更容易看出每一件活動執行情形。

Royal Pharmaceutical Society of Great Britain – The Pharmacy Practice Framework	
貢獻於有效的醫療照顧系統與公共衛生 1)遵守專業的責任與指引 2)貢獻於安全、合理與符合成本效益的使用藥品 3)提升、評值與改善社區的健康 4)鼓吹並支持能提升醫療結果的衛生政策 5)藥品的設計與藥理及藥劑特性與使用應能符合病人的需要 6)貢獻於教育、訓練與指導學生與醫療專業人員	貢獻於安全與有效的經營藥局或其他工作場所 1)貢獻於維持一個運作良好、健康與安全的工作環境 2)貢獻於管理同事與工作環境的其他資源 3)貢獻於建構系統來提供產品及高品質的服務 4)貢獻於提升組織與服務之知名度 5)盡力於減少出錯或疏失、不安全或違法執業
執行、監測與改變治療流程 1)支持病人來執行照顧計畫 2)依據照顧計畫支持與監測病人療效進展 3)紀錄發現情形、追蹤、建議、所提供資訊以及病人的結果	專業與治療的下決定 1)評估病人病情與需求 2)對適當的後續行動能得到病人同意
調劑藥品 1)評估處方藥品適當性 2)供應醫師處方藥品 3)對醫師所開的藥品對病人做指導	維持與改善專業的表現 1)計畫與執行個人專業成長的策略，來改善目前與未來的表現 2)扮演一個主動角色來監測與回顧所提供服務的品質，並發展與執行服務改善方案
調製、購得、儲存與發送藥物產品 1)臨時調製藥品製劑 2)購得與儲存藥物產品與製劑 3)發送藥物產品與製劑 4)廢棄藥品與製劑之回收	

Box reference 14: 專業執業架構 (College of pharmacists of British Columbia)

這專業執業架構(The Framework of Professional Practice)是一個優良藥事執業的藍圖。它描述出British Columbia藥師每天日常工作的內容，以及他們如何知道自己是否作的很好。這是所有College of Pharmacists of British Columbia programs and services 的基礎。(38)

有經驗執行許多種藥事執業的藥師協助發展了此架構，他們經由系統性的功能分析過程，作出描述：

＊藥師在做什麼 (What pharmacists do)

＊為何與何時他們在做它 (Why and when they do it)

＊他們如何做 (How they do it)

＊他們如何知道何時自己做的很好 (How they know when they perform well)

＊他們需要知道什麼才能將各種工作做得好 (What they need to know to perform all aspects of their work)

經由這個過程，他們草擬一份核心聲明來描述藥學專業存在的主要理由。他們描述為何藥師做他們所做的工作，他們如何做以及是為誰做。基於此目的聲明，他們定義出：

＊藥師所執行的主要角色 (Key roles pharmacists perform)

＊為達到每一角色藥師須執行的廣泛功能 (Broad functions that enable pharmacists to fulfill each role)

＊執行每一功能藥師須進行的日常活動 (Daily practice activities that contribute to each function)

＊每一個活動優良執業的指標 (Indicators of good practice for each activity)

＊藥師所需知識與執行技能的詳細說明 (Specifications for the knowledge and skills pharmacists need)

發展專業執業架構之目的在描述優良藥事執業(GPP)的組成。這不是在描述任何一位藥師的工作。有一些組成(components)與藥師做直接病人照顧最相關，而其他組成較與藥師執行研究、管理、教育或諮詢有關。B.C.省藥師確效了此專業執業架構，確認能反映當代的藥事執業。

"藥學專業存在的主要目的在協助民眾達到所期望的健康目標，藥師主要在與醫師及病人的共同合作之下，提供最新、合理、安全與符合成本效益的藥事服務，資訊與藥物產品。"

為維持優良藥事執業標準並符合這專業執業架構的標準，B.C.省藥師確認出五個核心角色，需要藥師直接的執行或監督執行。

1) 提供藥事照護 (Provide pharmaceutical care)
2) 調製或發送藥物製劑及產品(Produce and distribute drug preparations and products)
3) 貢獻於藥局的有效管理 (Contribute to the effective operation of the pharmacy)
4) 維持專業成長以及貢獻於協助其他人的專業成長 (Maintain professional development and contribute to the professional development of others)
5) 貢獻於醫療照護系統的有效運作(Contribute to the effectiveness of the health care system)

制定藥事執業之標準(Setting standards for pharmacy practice)

Box reference 15: 角色、功能及活動之定義

一個**角色**(role)的定義是一項社會與藥師服務對象所預期的藥師行為。

一個**功能**(function)的定義是一個特定領域，在其中藥師有直接責任去執行，並為確保良好執行而負責。

一個**活動**(activity)的定義是一套的行動，設計來達成一個特定的功能。

這份參考文件不是為發展出一份完整的藥事執業架構而寫的技術性指引，主要目的是帶入重要的資訊，讓各國藥學組織想要發展當地國自己的藥事執業架構時，需要工作與思考的方向 (39) (40) (41) (42) (43)。若要制定國家層級的藥事執業標準或評鑑機制，這是非常重要的。

這份文件指出有四個重要的角色藥師必須扮演的：

角色 1: 提供有效的藥物治療管理 (請看Table A)
角色 2: 準備、獲得、儲存、調劑及處置藥物產品(請看Table B)
角色 3: 維持與改善專業績效表現(請看Table C)
角色 4: 貢獻來改善醫療照顧系統與公共衛生的效果 (請看Table D)

基於之前由Working Group on GPP執行的前導性研究，一個描述藥師基本角色、功能與活動的參考文件已提出給所有國家的藥學組織參考。FIP 建議所有國家藥學組織採用這些特質再配合各國特性發展出自己的一個文件。對每一個活動，他們必須再發展出優良執業的指標(indicators)，這些指標必須因地制宜，能反映出該國的相關執業環境需求與國家專業標準，並有明確適當的定義。請參考 Box reference 16 的例子，指出在醫院的醫療系統環境下，藥事執業改善目標所使用之目的(goals)、目標(objectives)與指標。

各國家藥學組織也必須確認與澄清其他也工作在藥局的員工，他們的重要性與扮演角色。僅藥師知道 GPP 是不夠的，也必須要教育藥局內其他員工有關 GPP 的概念，因為藥局內大部分的工作是由他們再執行。

Table A: 角色1 - 提供有效的藥物治療管理 (Provide effective drug therapy management)	
功能 1.1: 評估病人健康狀態與需求	活動 1.1.1: 藥師應確保健康管理、疾病預防及健康的生活型態行為有加到病人評估及照顧流程中。
	活動 1.1.2: 藥師在病人評估階段應收集病人的一些特質資訊，如教育程度、文化信仰、識字程度、常用語言、擔心/害怕/顧慮/期望、及身體與精神上的功能情形。
功能 1.2: 管理病人的藥物治療	活動 1.2.1: 藥師應能運用一個電腦網路系統(地區/區域/國家) 基於找到最佳藥品使用證據，而能連結到標準疾病治療指引、治療計畫以及實證醫學網站。
	活動 1.2.2: 藥師應有一個重要角色在與處方醫師溝通，提供實證證據與最適當用藥的資訊，期望醫師能適當監測療效，以及適當修正處方內容。
	活動 1.2.3: 藥師應提供照顧的持續性，若病人轉院或回家藥師能提供後者前面醫院治療的用藥資訊。
功能 1.3: 監測病人進展與療效結果	活動 1.3.1: 藥師應考量病人診斷及病人特殊的需求，來評估病人對藥物治療的反應。
	活動 1.3.2: 藥師應盡量使用從多處來源獲得的相關臨床及病人數據，來協調有效的藥物治療管理，尤其是有許多不同醫師在照顧同一病人時。
	活動 1.3.3: 藥師在轉介病人給其他醫療專業人員時，應建立一套標準的操作流程。
功能 1.4: 提供病人教育	活動 1.4.1: 藥師應確保病人教育是在一個理想環境能有益於病人參與、學習及保護隱私。
	活動 1.4.2: 藥師應提供病人充分的健康、疾病與藥品資訊，以鼓勵他參與治療計畫的擬訂與決定。
Table B: 角色 2 - 準備、獲得、儲存、調劑及處置藥物產品 (Prepare, obtain, store, distribute and dispose medical products)	
功能 2.1: 準備臨時調製藥物製劑	活動 2.1.1: 藥師應確保藥物調製空間有適當之設計，能便於臨時處方藥品或製劑的調製，並能妥善維持空間的安全性與減少調製錯誤的產生，確保無菌製劑的無菌與安全性。
	活動 2.1.2: 藥師應確保調製出來的製劑有品質一致性，符合書面處方內容與主成分、儀器與調製過程的品質標準，包括無菌度之要求。
功能 2.2: 獲得與儲存藥物製劑與產品	活動 2.2.1: 負責採購的藥師應確保採購藥品過程是透明的、專業且符合倫理的，以提升公平性、獲取管道以及向相關法規與監督負責。
	活動 2.2.2: 負責採購的藥師應確保所採購藥品是有強烈的品質保證，並保證品質差的藥品不會採購或進入體系中。
	活動 2.2.3: 負責採購的藥師應確保採購藥品是有可信度高的資訊系統所支持，可提供正確、及時與易獲取的資訊。
	活動 2.2.4: 藥師應建立緊急應變計畫，以因應藥品短缺及緊急採購之需求。
	活動 2.2.5:藥師應確保醫院所使用藥品都有適當的儲存環境。

功能 2.3: 調劑與發送藥物製劑與產品	活動 2.3.1:藥師應確保所有藥物製劑在調劑與發送上，都以負責與安全的態度處理。
	活動 2.3.2: 藥師應建立一個有效率的調劑與發送系統，包括書面的政策與流程。若有藥品懷疑品質不好或屬於偽藥需要回收時，能立刻與有效的追蹤到並回收藥品。有指定專人負責藥品回收。
	活動 2.3.3: 藥師應與製藥廠商發展一套不斷貨系統，以備重大災難發生時的應變策略。
功能 2.4: 過期廢棄藥品之處置	活動 2.4.1: 藥師應確保藥品庫存監控系統能有定期的檢查失效日期，以便找出快過期藥品而從儲架上移除。
	活動 2.4.2: 藥師應確保須回收之藥品都已從所有庫存位置移除。
	活動 2.4.3: 藥師應建立一套安全處置過期廢棄藥品的回收制度，並能鼓勵病人與大眾將家中過期與不再使用藥品回收至藥局。
Table C: 角色 3 - 維持與改善專業績效表現 (Maintain and improve professional performance)	
功能 3.1: 計畫與執行持續專業成長[3]的策略以改善現在與未來的績效表現	活動 3.1.1: 藥師應認知要接受終生的持續教育，能呈現持續教育學分數或持續專業成長的證明，來提升執業技能與表現。
	活動 3.1.2: 藥師應採用步驟更新自己知識與技能，包括主流治療知識與中藥及另類療法的治療選擇。
	活動 3.1.3: 藥師應採用步驟更新自己知識，並能接受新科技之使用與藥事執業自動化之發展。
Table D: 角色 4 -貢獻來改善醫療照顧系統與公共衛生的效果 (Contribute to improve effectiveness of the health care system and public health)	
功能 4.1: 遵守國家制訂的專業義務，指引與法律要求	活動 4.1.1: 藥師應確保其專業行為符合藥學倫理信條所制訂的規範
功能 4.2: 致力於提升藥物使用之安全、合理與符合成本效益	活動 4.2.1: 藥師應能持續接觸到有關藥物使用之安全、合理與符合成本效益的相關實證證據，如：藥物資訊參考書籍/雜誌，標準疾病治療指引，網路連結
功能 4.3: 鼓吹與支持國家政策來提升醫療效果	活動 4.3.1: 藥師應參與公眾或專業團體來增進、評估與改善社區的健康情形
	活動 4.3.2: 藥師應與其他醫療專業人員合作，共同努力來提升醫療效果
功能 4.4: 廣泛傳播已評估過後的正確藥品資訊與各類自我照護資訊	活動 4.4.1: 藥師應確保提供給病人與大眾的資訊是客觀的、可看得懂的、非促銷性的、正確且適當的
	活動 4.4.2: 藥師應發展疾病管理、促進健康和疾病預防的教育性教材，可運用到廣泛的病人族群，年齡層與識字程度。
	活動 4.4.3: 藥師應教育病人如何評估與使用網路查詢到的醫療照顧資訊(包括藥品資訊) 並強烈鼓勵病人與藥師討論他們所查得的資訊
	活動 4.4.4: 藥師應協助病人及其醫師來獲得並嚴謹評估資訊，以滿足其個人需要

Box reference 16: 美國ASHP的醫療系統藥師2015目標–醫院藥事執業指標

醫療系統藥師 2015 目標是美國 ASHP 的一個重要里程碑，來顯著提升醫療系統內的藥事執業。這個計畫包括 2015 年要達到的 6 個關鍵目標(goals)及 31 項目的(objectives)，這是從"ASHP 願景聲明"所衍生出來的。這聲明的主要議題是：醫療系統藥師應協助藥品使用更有效、科學及安全，並願意貢獻於社區來有意義提升公共衛生。

Goal 1	Increase the extent to which pharmacists help individual hospital inpatients achieve the best use of medications.
Goal 2	Increase the extent to which health-system pharmacists help individual non-hospitalized patients achieve the best use of medications.
Goal 3	Increase the extent to which health-system pharmacists actively apply evidence-based methods to the improvement of medication therapy.
Goal 4	Increase the extent to which pharmacy departments in health systems have a significant role in improving the safety of medication use.
Goal 5	Increase the extent to which health systems apply technology effectively to improve the safety of medication use.
Goal 6	Increase the extent to which pharmacy departments in health systems engage in public health initiatives on behalf of their communities.

Example of qualitative monitoring of progress for Goal 1:

Goal 1	Increase the extent to which pharmacists help individual hospital inpatients achieve the best use of medications.
Objective 1.1	Pharmacists will be involved in managing the acquisition, upon admission, of medication histories for a majority of hospital inpatients with complex and high-risk medication regimens* in 75% of hospitals.
Objective 1.2	The medication therapy of a majority of hospital inpatients with complex and high-risk medication regimens will be monitored* by a pharmacist in 100% of hospitals.
Objective 1.3	In 90% of hospitals, pharmacists will manage medication therapy for inpatients with complex and high-risk medication regimens*, in collaboration with other members of the health-care team.
Objective 1.4	Hospital inpatients discharged with complex and high-risk medication regimens* will receive discharge medication counseling managed by a pharmacist in 75% of hospitals.
Objective 1.5	50% of recently hospitalized patients (or their caregivers*) will recall speaking with a pharmacist while in the hospital.
Objective 1.6	In 90% of hospitals, pharmacists will ensure that effective medication reconciliation* occurs during transitions across the continuum of care.

For more information on the objective indicators for each goal, please visit: http://www.ashp.org/2015

強化藥事執業的法律基礎: 國家藥品政策及藥師執業政策

簡介

在2008年的聯合國報告: Delivering on the Global Partnerships for Achieving the Millennium Development Goals 特別指出目前在公立及私立醫療環節是否有藥可用存在很大的差距,同時藥品價格也有很大差異造成許多窮人無法負擔基本需要的藥品(44)。這報導也指出由藥師做**學名藥取代**是一個重要政策，來確保可獲得能負擔之必須藥品，這政策應有更多國家來執行。

世界衛生組織的最新預估值顯示公立醫療所提供之藥品只涵蓋了1/3的必須藥品，而私立醫療的藥品能涵蓋2/3。(45)

就是能得到藥品的人，當需要時有可能得到是不正確或劑量不適當的藥品。許多人購得或經由醫師處方藥師調劑得到的藥品，並不見得適合他的需要。有些人獲得多種藥品但事實上它只需要一種藥品，其他人使用藥品但承擔了不需要的風險。在2007年第60th World Health Assembly中發表的一份合理使用藥品之進度報告，WHO數據顯示在非洲、亞洲及拉丁美洲的基層醫療體系內，在許多普通疾病治療的所有病人中，只有40%是符合臨床治療指引的；而這些情況在近15年來沒有改善。在2007年5月WHO會員國因此通過一個合理使用藥品的解決方案WHA60.16，要求會員國執行下列行動：

Box reference 17: 從WHA 60.16摘要出合理使用藥品的解決方案

"1. 要求會員國:

能考慮建立及/或強化一個國家的官方藥品法規權責單位及一個完整國家計劃及/或跨醫療專業團體，加入國內社福及專業團體，來監督及提升合理的藥品使用；

能發展及強化已存在的合理使用藥品訓練計畫,並確保這些內容已編列在所有醫療專業人員及醫學生的教育課程中，包括繼續教育內。同時鼓勵對大眾教育合理使用藥品；

能立法新的或強化已存在的法律來廢止不正確、誤導人或不符合倫理的藥品廣告，來監督藥品的行銷行為，並發展與執行計畫來提供獨立、非促銷性藥品資訊；

能發展並執行國家政策與計畫來改善藥品使用,包括臨床治療指引及必需藥品目錄。針對公立及私立的醫療體系，結合提供者與顧客，強調多面向的介入。能考慮發展及強化醫院的藥事委員會來鼓勵合理藥品的使用。"

這些是重要的全球性對藥學專業的要求，期望從國家層級來對合理用藥產生衝擊。更重要的是，這些要求能形成建立國家「優良藥事執業規範」的基本依據，是專業標準或法規依據的重要國家藥品政策(37)。這能讓民眾的用藥更容易獲得(公平取得可負擔的必須藥品)，有品質(安全、有效、有高品質的藥品)，及適當使用(鼓勵讓醫療專業人員及民眾使用治療效果佳及符合成本效益的藥品)。

強化藥事執業的法律基礎

有些國家的「優良藥事執業規範」是國家藥品政策的重要組成之一。其中一個原因是藥師、藥師助理及開處方護理師都站在一個提倡合理用藥的立場，他們的角色應該更受到重視。在開發中國家，藥師與藥師助理的訓練及督導必須要被重視與強調。他們的適當技能與訓練需求必須首先要確定出來(47)。國家藥學專業組織必須與政府藥政組織合作，來發展、更新與執行這些國家政策。

Box reference 18: 藥事執業與法規 (48) (49)

藥事法規描述著藥師日常執業的基本要求，同時也清楚定義藥師與其所服務大眾的關係。當做醫療專業人員，藥師是被高度管理的，因為在調劑或藥事照護的一點小疏失可能會要人命。做為國家藥品供應與使用之監護人，藥師必須要接受強烈法規的要求，因為藥師所控制的產品比一般商品具有更高品質標準的要求。藥師必須讀藥事法規，因為透過法律要求，社會已規範出藥師的哪些行為是可被接受的，而藥師若違反這些規範就必須負起責任來承擔法律處置。

可再閱讀下列文章：

Abood, Richard. *Pharmacy Practice and The Law, Fifth Edition.* US : Jones & Bartlett, 2008. ISBN 0763749788.

Pharmacists, pharmaceuticals, and policy issues shaping the work force in pharmacy. Manasse HR Jr, Speedie MK. 12, 2007, Am J Health Syst Pharm, Vol. 64, pp. e30-48.

Box reference 19: 在國家藥品政策制定流程中與藥師相關的重要政策議題(47)

在整個藥品政策制定流程(不只是發展階段)會與各種有興趣團體及利害關係人有許多諮詢、對話及協商的過程。這些包括其他政府部門(如高等教育、貿易及工商業)，醫師，藥師，護理師，當地及國際的製藥業，藥品代理業，學校教育，非政府組織，專業學會及病人團體。

國家政府組織，如衛生署醫政處、藥品法規單位(FDA)與各縣市衛生局與藥政單位，都是藥品政策執行的重要參與人。

法律與法規能確保任何一方的責任、擔任資格、權利及角色都有明確定

義並被承認(包括醫療執業人員，藥師及藥品法規權責單位)。在藥品製劑方面的法律最關心的是能確保有療效、安全及高品質的藥品能進入市場，同時能提供出正確的藥品資訊。

必須藥品的選擇流程也極為重要。一個常設委員會必須成立起來給予技術上的意見。這委員會成員應來自不同的領域，包括醫學、護理、臨床藥理、藥學、公共衛生、病人團體及基層醫療工作者。時常私立團體也應該包括進來。許多國家的大多數群體是由私立團體來提供藥品，這包括私立的大盤商，經銷商，藥師與非正式的賣藥人。

改善醫療專業人員的基本訓練是很重要的策略來增進合理藥物使用。必須藥品(essential drugs)的概念與實際運用必須加入所有醫療從業人員的課程之中。

在一些缺乏藥師與藥師助理的國家，處方藥可能由未經正式訓練的人來賣藥，則基本的在職訓練必須對他們執行。運用檢查清單(checklists)及簡單的書面資料做實務訓練，可協助他們將工作做好並有效的與病人溝通。

若將開處方及調劑功能都給予同一位專業人員，會導致過度開處方藥，因為會有經濟誘因賣更多藥或更貴的藥。因此建議這兩個功能要分的愈開愈好，但極偏遠地區要除外，因為單獨藥局的市場太小。**政府應考慮採用法律途徑來區分開處方與調劑功能**，來移除強大的經濟誘因。例如調劑醫師與開處方藥師兩種都會有過度開處方的趨勢。

學名藥政策、藥價政策與調劑費結構，可以用來鼓勵使用必須藥品並鼓勵多開學名藥以及做學名藥取代。

發展及執行一個藥品政策需要高度經驗與資格的專業人員，包括政策決定者、醫師、藥師、藥師助理、臨床藥理學家、醫療相關人員、經濟學家及研究者。

藥事執業品質管理架構的核心原則 (Core principles of a pharmacy practice quality management framework)

簡 介

在前面章節討論設定優良藥事執業的標準，已描述藥局服務或活動的一般目標。為了確保這些目標可以達到，有需要建立標準化的服務或活動執行內容。這標準化可以保證藥局內所執行活動而達到的結果是民眾需要的，其品質是正面的並且能符合顧客的需求。

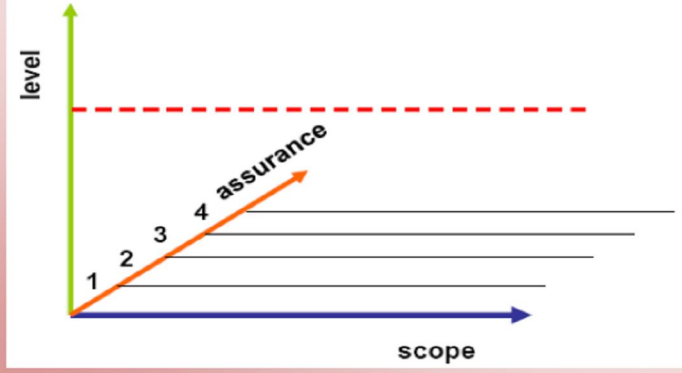
這「顧客」可能是進到社區藥局或在醫療機構的病人。由於藥事服務的設計是從國家層面去做規劃，所以分析顧客的需求以及服務品質的要求，也必須從整體國家層面來考量。整個專業藥事服務有一些是共同的(如調劑)，但也有一些會因執業地點不同而有不同的程度表現。

通常在國家法律層次考慮藥學專業及藥局執業，會用最少能提供哪些藥事服務的描述。這些法規很少會精準的指示這些服務會如何執行來達到要求。因此，國家的藥學專業團體應該要建構一個品質管理系統讓藥局使用，並發展策略計畫來發展新藥事服務。

需求評估 (Needs assessment)

顧客的需求會因不同文化或國家而有許多差異，因此醫療照護系統的建構也都有差異，同時對藥事服務的期望也有差異。若要開始規劃國家標準與品質管理系統，第一步驟就是要先做需求評估。在藥品供應、服藥配合度或促進健康上等等，藥師的角色是什麼？我們如何發展服務的內容或需做的行為來提升服務品質？基於需求評估，國家藥學專業團體及社區藥局可選擇他們可以提供的服務及適當程度的服務。這可以用下圖做描述：

Box reference 20: Needs assessment framework



依據需求評估架構(請看Box Reference 20)，國家藥學組織必須定義該國藥事執業的要素(elements)有哪些，每一項要素可達到的品質程度有哪些，每一項要素所要求的品質保證程度是什麼。有這些決定，則所需要的標準以及所要建構的系統來管理欲達到之品質才能開始規劃。

品質管理系統 (Quality management systems)

品質管理系統與標準就像是ISO 9000系列以及全品質管理(Total Quality Management, TQM) 模式已發展出來將品質標準全球化。這 ISO standards 4原先是發展出來用於工業生產，但現在已可用於服務執行的標準化。

有關藥事服務的品質標準，建議各國的國家藥學組織應採用國際標準，然後修正用於自己國家的藥學環境。建議發展與執行一個品質管理系統的流程，可參考下列幾個步驟：

1. 決定顧客與其他有興趣團體的需求與期望
2. 建立專業團體的品質政策與品質目標
3. 決定所需要的流程與責任來達到品質的目標
4. 決定與提供各類需要的資源來達到品質目標
5. 建立方法來測量每一流程的有效性與效率
6. 運用這些測量方法來決定每一流程的有效性與效率
7. 決定方法來避免無法配合的情境並移除掉那些造成原因
8. 建立並運用一個流程來持續改善這品質管理系統

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4 The basic references are the standard ISO 9001-2000 "Quality management systems. Requirements" and the standard ISO 9000 "Quality management systems – fundamentals and vocabulary ", together with the International Workshop Agreement IWA1, "Quality management systems – guidelines for process improvements in health service organizations".

Box reference 21: 藥事服務的認證 (Certification of pharmaceutical services)

在某些國家，例如葡萄牙，對於認證藥事服務愈來愈有興趣，而不是用 ISO 9000 系列來作認證。藥事服務認證牽涉到針對某些服務是運用 Service Norm or Technical Specification (http://www.sgs.com/)中的指示來執行。事實上，ISO 9001 認證是在認證運用於藥局組織架構的"方法"，而服務認證是在認證由藥師/藥局提供一些服務給病人/顧客。國家藥學組織可發展連鎖店或跨國組織的"多點式"經營模式，讓某些流程中央化由特殊中央組織來執行，如對抱怨的處理、執行糾正或預防行動、管理持續教育等，而讓藥局(有些藥局的藥師人數很少)來處理日常營運的流程。

品質管理原則 (Quality management principles)

在ISO-standards共有 8 個品質管理的原則。摘要描述如下：

1. 以顧客為中心

藥局與藥師仰賴他們顧客的光臨才有生意，因此應瞭解目前與未來顧客的需要，應滿足顧客的要求並盡量超越顧客的期望。

2. 領導統御

藥學領導者建立統一的專業團體發展目標與方向，他們應創造並維持內部的環境，讓其組成的同事們完全參與來達到該團體的奮鬥目標。

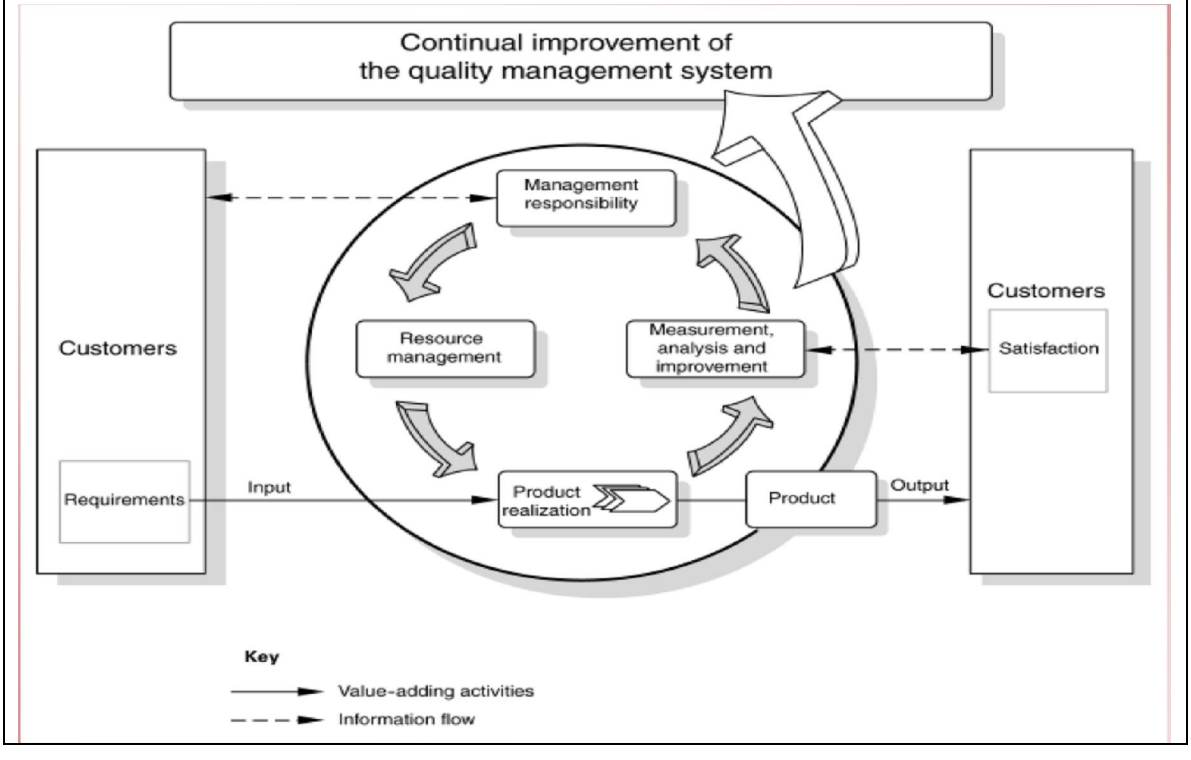
3. 同事的參與

在藥學界各領域服務的同事們都是重要的組成份子，他們的全力參與貢獻是創造藥學發展與利益的重要資產。

4. 採用流程的概念

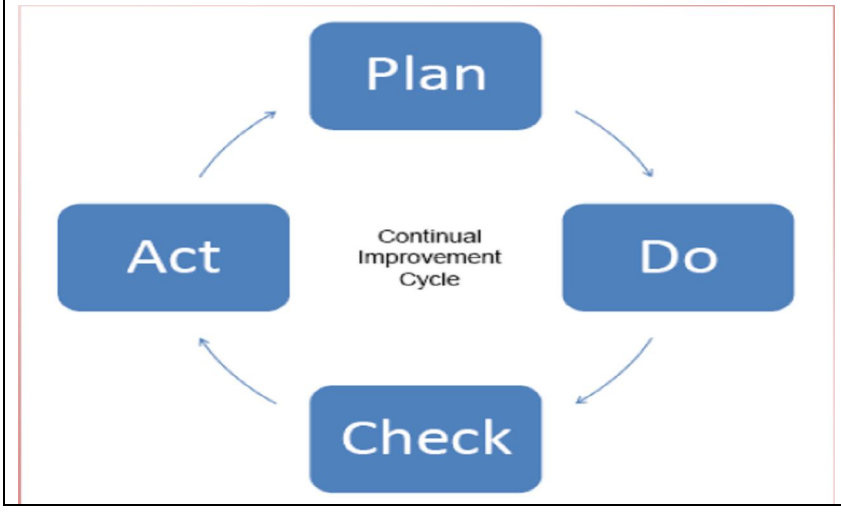
在藥局內的所有活動可被描述成流程，在這些流程中，資源被使用來將投入轉換成產出。一般說來有兩種流程：主要流程(main processe)及支持流程(supporting processes)。

Box reference 22: 一個以流程為基礎的管理系統模式 (50)



在藥局內的主要流程可能是“物品的流動”、“資訊的流動”及“健康促進”。一個典型的支持性城市清潔與人事管理。這流程與達到流程結果所需的要求應及早決定，並規律地評估成效。在每一流程可運用戴明的方法“Plan-Do-Check- Act”來保證持續的追蹤及發展新流程。

Box reference 23: 戴明的 Plan-Do-Check-Act 循環



5. 以系統步驟做管理

   確認、理解及管理有相互關係的不同流程，形成一個系統管哩，可有效並有效率的讓藥局經營達到其營運目標。

6. 持續改善

   持續改善藥局內的整體表現，應是品質管理的永久理念。

7. 以事實根據作決定

   有效的決定應基於數據與資訊的分析。品質系統應建構於在流程上及執行結果上，能持續產出穩定可信賴以及最新的數據與資訊。

8. 與供應商建立互蒙利益的關係

   藥局與其供應商之間是相互依賴與互蒙利益的關係，這能增進雙方能力共創價值。這種關係對物品供應鏈以及醫療照顧團隊有最終的重要性，並應基於雙方的相互尊重與專業特質。

附錄 1：37 個國家 GPP 標準的資訊

Country	**Argentina**
Dated	30/04/2008
Contact	Jose Ruggieri
Email	joseruggieri@cofa.org.ar
Source	National association in Argentina
Weblinks	www.cofa.org.ar
Summary of data available	There are three GPP documents from Argentina. Two of them regard good dispensing practice and good practices for the manufacture/preparation of medicines in community and hospital pharmacies, which will be included in the next version of the Argentinean Pharmacopoeia. These two documents were elaborated jointly by the national pharmaceutical organisation and the MoH. The third document is the guidelines for hospital pharmacy. They are currently working with the MoH in revising the current standards and creating pharmacies in all healthcare centres with in-patients

Country	**Australia**
Dated	04/05/2009
Contact	Kay Sorimachi
Email	kay.sorimachi@psa.org.au
Source	Pharmaceutical Society of Australia
Weblinks	http://www.psa.org.au/
Summary of data available	Competency Standards for Pharmacists in Australia 2003 – accessible at www.psa.org.au/site.php?id=1123 Professional Practice Standards 2006 – accessible at www.psa.org.au/site.php?id=1094

Country	**Austria**
Dated	30/04/2008
Contact	Sabine Horak-Harzhauser
Email	Sabine.Horak-Harzhauser@apotheker.or.at
Source	Österreichische Apothekerkammer
Weblinks	www.apotheker.or.at
Summary of data available	Firstly national standards on Good Pharmacy Practice are in general regulated in the Austrian Regulation on the operation of pharmacies 2005 ("Apothekenbetriebsordnung 2005"), which is binding law in Austria. According to the fact, that pharmacies are responsible for the supply of pharmaceutical and medicinal products, the production and distribution of drugs and their storage and administration . All these functionsare regulated. Because pharmacies also provide comprehensive customer counsel on general health issues, the Regulation on the operation of pharmacies 2005 secondly sets standards for pharmacists working in pharmacies and for the pharmaceutical care. The obligations of confidentiality, avoidance of incompatibilities as well as the obligation of continuing education are set national (minimum) standards. For further information the Regulation is enclosed. Unfortunately there is no English version available. Thirdly there exist guidelines on sales promotions and advertisements made by pharmacies. The national standards can be found on our website www.apotheker.or.at -> Themenbereiche -> Information der Rechtsabteilung -> Apothekerberufssitte as well as in the relevant law such as the Austrian Chamber of Pharmacists Act and Medicinal Products Acts. There is a disciplinary committee established at the Austrian Chamber of Pharmacists which observes these standards.

Country	**Bosnia and Herzegovina**
Dated	15/04/2008
Contact	Sanja Stjepanovic
Email	sinapsa@bih.net.ba
Source	Pharmaceutical Association of FB&H
Weblinks	
Summary of data available	There is an electronic version of GPP booklet. “Professional Targets on Good Pharmacy practice for Bosnia and Herzegovina“which has established national standards for pharmacists working in community and hospital pharmacies. It was adopted at country level in 1999 by members of 3 existing national associations in Bosnia and Herzegovina. B&H Law on Health care states that pharmacists are obliged to work in accordance with GPP Standards.

Country	**Brazil**
Dated	15/04/2008
Contact	Jaldo de Souza Santos
Email	wanilda@cff.org.br
Source	National association in Brazil (CFF)
Weblinks	
Summary of data available	Reference to a national resolution (law) 357, the national association has established national standards for GPP. Last revised 20th April 2001. Only available in Portuguese

Country	**Canada**
Dated	17/04/2008
Contact	Barbara Scollick
Email	scollick@gmail.com
Source	Canadian Pharmacists Association/NAPRA
Weblinks	www.napra.org
Summary of data available	The Canadian Pharmacists Association (CPhA) is a national professional voluntary association and as such we do not develop standards of practice; however, the National Association of Pharmacy Regulatory Authorities (NAPRA) develops standards for pharmacists in Canada. NAPRA’s website with some of standards is http://napra.org/docs/0/95.asp and you may wish to contact them for further information. Some of their documents you may be interested in are: Professional Competencies for Canadian Pharmacy Technicians at Entry to Practice Guidelines to Pharmacy Compounding - October 2006 Supplemental Standards of Practice for Schedule II and III Drugs - June 2005 Model Standards of Practice for Canadian Pharmacists - April 2003

Country	**Costa Rica**
Dated	10/05/2008
Contact	María Lorena Quirós Luque
Email	direccionejecutiva@colfar.com
Source	National association in Costa Rica (COLEGIO DE FARMACEUTICOS)
Weblinks	www.colfar.com
Summary of data available	

Country	**Croatia**
Dated	22/04/2008
Contact	Maja Jakševac Mikša
Email	maja.jaksevac-miksa@zg.t-com.hr
Source	Croatian Pharmaceutical Society
Weblinks	

Summary of data available	The GPP guidelines are very old (from 1997) and they have only a printed version. It was issued by Croatian Chamber of Pharmacists and printed by Croatian Pharmaceutical Society as a supplement to our professional journal Farmaceutski glasnik (vol. 53, 7/8 1997). They intend to create a new version soon, after the revision of the Ethical Code which is in the course of preparation.

Country	**Cuba**
Dated	26/04/2008
Contact	Eneida Pérez Santana
Email	farma@hha.sld.cu
Source	Sociedad Cubana de Ciencias Farmacéuticas
Weblinks	
Summary of data available	The GPP guidelines are only available in Spanish. There is one specific to community pharmacy (revised 2005) and one specific to hospital pharmacy

Country	**Czech Republic**
Dated	29/04/2008
Contact	Stanislav Havlí?ek
Email	havlicek@lekarnici.cz
Source	Czech Chamber of Pharmacists
Weblinks	www.lekarnici.cz
Summary of data available	Czech Chamber of Pharmacists has new leadership since November 2007. We established a working group for standardization. This group is working on those standards right now. We hope we will finish it end of this year. Last year we just finished algorithm design (guidelines) for dispensing each pharmacotherapeutic group. Unfortunately those materials are only in Czech language

Country	**Denmark**
Dated	29/04/2008
Contact	Peter Jørgensen
Email	pj@apotekerforeningen.dk
Source	Association of Danish Pharmacies
Weblinks	
Summary of data available	The philosophy of the FIP guidelines for Good Pharmacy Practice (GPP) has for a number of years been a central part of and implemented in the Danish legislation for the pharmacies (Pharmacy Act) and the drug legislation (Medicines Act). Therefore all in all most elements in the FIP guidelines for GPP are part of the daily work in Danish pharmacies. Let me give some examples: According to the Danish legislation for pharmacies and the drug legislation there are standards for: * quality of prescribing data provided to the pharmacist * the preparation of formularies on medicines * educational programs for health professionals * confidentiality of data relating to individual patients * reporting of adverse events, medications errors, defects in products quality and diction of counterfeit products * manufacture of medicines * preparation and quality assurance of extemporaneous preparations * sources of supply of medicines and other items * disposal of unused pharmaceutical products and pharmaceutical waste * medication records Furthermore the Association of Danish Pharmacies in 2006 approved an overall strategy for community pharmacies in Denmark with 3 visions: A professional, a customer-oriented and an ethical vision. The vision about professional competence is realised by pharmacists by * always uncovering the need of the individual customer for counselling and information, * taking joint responsibility for the customer's drug treatment and patient safety, * offering a relevant selection of health promoting and disease preventing services and * cooperating with other actors in the health care sector. Finally I would like to inform you briefly about our work in the Nordic Pharmacy Association where we

	together with our colleagues from Finland, Norway and Sweden have adopted several sets of professional "Guidelines for Pharmacies in the Nordic Countries" on patient safety, on medicines profiles and on information and counseling. These guidelines are to a large extent inspired by GPP and are even structured in the same way (society, patients, processes and staff)
Country	**Dominican Republic**
Dated	01/05/2008
Contact	Lourdes Valenzuela
Email	lourdesvalenzuela_mateo@hotmail.com
Source	Pharmaceutical Association of the Dominican Republic
Weblinks	
Summary of data available	In brief, there are regulations for hospital pharmacy and community pharmacy. In our country, the field of practice that is best organised is hospital pharmacy, since it has had its own professional society for a number of years. As for community pharmacy, the situation is a complete disaster: according to a study by the Ministry of Health and PAHO from 2005, 50% of community pharmacies in our country are illegal and this figure has not changed since then. Naturally, this causes a very bad impression on patients/users since medicines are not dispensed by competent professionals. Received attached the regulations in force, under the General Law on Healthcare, Law 42-01, regulation 246-06.
Country	**Eritrea**
Dated	05/05/2008
Contact	Samuel Girmay
Email	gsamu4@yahoo.com
Source	Eritrea pharmaceutical association
Weblinks	
Summary of data available	Currently we don't have a separate document on Good Pharmacy Practice in our country Eritrea. But we do have other documents which we use as a guideline to practice our pharmaceutical services. Such documents include National Medicines Policy, guideline for Good Manufacturing Practice (GMP) and Logistic Management Manual. Please find attached the document for the National Medicines Policy; I think that is the most important one.
Country	**Finland**
Dated	30/04/2008
Contact	Ingrid Wiberg
Email	ingrid.wiberg@apteekkariliitto.fi
Source	Suomen Apteekkariliitto - The Association of Finnish Pharmacies
Weblinks	
Summary of data available	I submit The Ethical Guidelines as drawn up by The Association of Finnish Pharmacies and thus guiding the functions and work in the privately owned community pharmacies in Finland. The committee on pharmaceutical affairs at The Association of Finnish Pharmacies meets at the end of May, there we will discuss this matter further and after that submit our guidelines/strategies on: The Pharmacy and Health Promotion, Guidelines for a Professional Community Pharmacy in Finland and The Community Pharmacy – Expert on Health Care. These standards however are at the moment not available as electronic files

Country	**France**
Dated	29/04/2008
Contact	Florence PETIT
Email	dap@ordre.pharmacien.fr
Source	Ordre national des Pharmaciens
Weblinks	www.ordre.pharmacien.fr
Summary of data available	Further to your request for national standards for Good Pharmacy Practice, I am pleased to send you enclosed relevant documents and link on that topic: For hospital or community pharmacists: Bonnes pratiques de préparations For community pharmacists : Guide d'assurance qualité officinale http://www.ordre.pharmacien.fr/upload/Syntheses/90.pdf website EQO http://www.eqo.fr/accueil Guide de stage de pratique professionnelle en officine - Pharmacie générale - Officine - 6ème année http://www.ordre.pharmacien.fr/upload/Guidestage/guide-stage-6eme-annee.pdf Recommandations pour l'aménagement des locaux de l'officine http://www.ordre.pharmacien.fr/upload/Syntheses/219.pdf Information relative aux prix des médicaments http://www.ordre.pharmacien.fr/upload/Syntheses/151.pdf For hospital pharmacists: Bonnes pratiques de pharmacie hospitalière « Guide de pratiques professionnelles sur la prise en charge thérapeutique du patient hospitalisé : le circuit du médicament » élaboré sous l'égide de la DHOS (2004) et consultable à l'adresse : http://www.sante.gouv.fr/htm/dossiers/secumed/accueil.htm (mot de passe : dhosecumed1). Guide méthodologique rédigé par le SYNPREFH « sécurisation du circuit du médicament », version n° 2 de mai 2006 disponible sur le site du SYNPREFH à l'adresse : http://www.synprefh.org/documents/circmed_guide_synprefh_200605.pdf Le livre blanc "Pharmacie Hospitalière - Horizon 2012" édité par le SYNPREFH ne sera disponible qu'après le 22 mai 2008. Recommandations de bonnes pratiques appliquées au transport des produits de santé http://www.ordre.pharmacien.fr/upload/Syntheses/277.pdf Recommandations relatives aux bonnes pratiques de gestion des produits de santé soumis à la chaîne du froid entre 2 et 8° Chttp://www.ordre.pharmacien.fr/upload/Syntheses/216.pdf

Country	**Germany**
Dated	28/04/2008
Contact	Christiane Eckert-Lill
Email	C.Eckert-Lill@abda.aponet.de
Source	ABDA
Weblinks	
Summary of data available	The Ordinance on the Operation of Pharmacies (Apothekenbetriebsordnung), which is a federal ordinance, gives general standards on Good Pharmacy Practice, for example – state, size and equipment of pharmacy premises – qualification and competences of the personnel – information sources – preparation and quality assurance of extemporaneous preparations rsp. Drugs kept in stock in larger quantities – stockpiling – storage – delivery of drugs – information and advice – pharmaceuticals risks and handling of non-marketable drugs – documentation – stand by duty The Federal Chamber of Pharmacists has edited 18 Guidelines on Quality

	Assurance (including comments and SOP referring to the main topics – information and advice, – pharmaceutical care, – preparation and quality assurance of drugs, – diagnostic testing. They are recommendations and shall help to establish a quality assurance system focusing on pharmaceutical services. But they can be used in pharmacies without quality assurance system as well. The Guidelines on Quality Assurance and other relevant information are available on the website www.abda.de/bak_leitlinien.html
Country	**Ireland**
Dated	30/04/2008
Contact	Damhnait Gaughan
Email	Damhnait.Gaughan@pharmaceuticalsociety.ie
Source	Senior inspector for the Ireland pharmaceutical Society
Weblinks	
Summary of data available	The regulation of the practice and profession of pharmacy in this jurisdiction is undergoing a period of significant change. The legislative framework was significantly updated with the commencement of the Pharmacy Act 2007, and this provides for a more robust regulatory environment. This will necessitate and has instigated the commencement of work in the area of standards. I would refer you to www.pharmaceuticalsociety.ie where you will find under the Standards heading documentation which you may find of interest, specifically http://pharmaceuticalsociety.ie/Standards/upload/File/Standards%20Guidelines,%20FINAL.pdf and http://pharmaceuticalsociety.ie/Standards/upload/File/CodesOfEthics&Practice_01.05.doc
Country	**Israel**
Dated	12/04/2008
Contact	Howard Rice
Email	howard@zahav.net.il
Source	National association in Israel
Weblinks	
Summary of data available	Whilst our national organization has not implemented these guidelines, it is now a mandatory demand of the Ministry of Health for pharmacists to adopt the GPP standards as set out by FIP/WHO. These demands are particularly the case with preparation of medications (extemporaneous), labelling and recording. Physicians can only write prescription by computer or type writer or if not only in capital letters- to avoid mistakes. There is also a statutory requirement for all new pharmacies or those that undergo "shop fitting" renovations, that a consultation room be included. Whist the amount of consultations is increasing rapidly in pharmacies, it has not reached 100% and it is difficult to inspect this. The national GPP document is in Hebrew and are available on the Ministry of Health website http://www.health.gov.il/forms/forms.asp?Category_Id=2&Element_type_id=2
Country	**Italy**
Dated	24/04/2008
Contact	Giuseppe IMPELLIZZERI
Email	box@federfarma.it
Source	Federfarma
Weblinks	

Summary of data available	Our Federation after the approval of GPP guidelines by FIP and consequently by PGEU, decided to set up a Quality Charter of our pharmaceutical services in 1994, where we began to ask to our members (only community pharmacists) to engage themselves in offering tailored services to their patients taking into account the model of pharmaceutical care. Other relevant points in our Charter concern the promotion of health, the help offered to patients in their self-care activity, the accurate control of the prescription, the continuous contact with the prescriber and so on.
Country	**Jordan**
Dated	22/04/2008
Contact	Samira Goussous
Email	s_goussous@ads.com.jo
Source	Jordan pharmaceutical association
Weblinks	
Summary of data available	The text is in Arabic it includes all the information and definition of GPP and the pharmaceutical care, Code of ethics etc
Country	**Republic of Macedonia**
Dated	22/04/2008
Contact	Maja
Email	info@farmacevtskakomora.com
Source	Pharmaceutical Chamber of Macedonia
Weblinks	
Summary of data available	The Republic of Macedonia hasn't yet established national standards for pharmacists working in community and pharmacy settings. The new Law of medicines and medical devices (2007) defines the necessity of establishment and implementation of such standards. Further more, the endorsed HEALTH STRATEGY OF THE REPUBLIC OF MACEDONIA, 2020, SAFE, EFFICIENT AND JUST HEALTH CARE SYSTEM, by the Government of RM, contains the whole chapter, explaining the pharmaceutical care and priorities for implementation. Therefore, a committee is formed by the Minister of Health, to set up these standards, and Pharmaceutical Chamber of Macedonia is actively involved in all the activities. Currently the Pharmaceutical Chamber of Macedonia runs a project sponsored by the World Bank, as training workshops, regarding these issues - promotion of GPP, health, patient self care, pharmaceutical care, improving prescribing and medicine use by pharmacist's activities. FIPs "GPP in developing countries" document is used as one of the reference materials.
Country	**Mongolia**
Dated	29/04/2008
Contact	D.Dungerdorj
Email	dungerdorj@hsum.edu.mn
Source	Mongolian pharmaceutical association
Weblinks	
Summary of data available	Mongolian Pharmaceutical Practice is using the Mongolian National Standards (MNS), which are based on the FIP/WHO GPP guidelines: 1.Good Manufacturing Practices for pharmaceutical products – MNS 5524: 2005(Mongolian GMP) (Since November 10, 2005). 2. General Principles for drug procurement organizations – MNS 5530: 2005(Since December 01, 2005). 3. General Principles for Pharmacy – MNS 5260: 2006 (since January 10, 2007). These National Standards not translated in English, so we could not send you above mentioned MNS copies.
Country	**The Netherlands**

Dated	24/10/2008
Contact	F. (Frans) J. van de Vaart
Email	f.j.van.de.vaart@winap.nl
Source	KNMP Scientific Institute
Weblinks	www.knmp.nl
Summary of data available	The quality care system in The Netherlands is based on the scheme of the Council for Quality Assessment in Healthcare (HKZ for community pharmacies, version 2003), the ISO 9001:2000 standards and their requirements relating to pharmacies, the Dutch GPP 2006 and its related guidelines. The Dutch model is derived from the EFQM model (European Foundation for Quality Management). The development and utilisation of the INK-model is supported by The Dutch Institute for Quality (INK). The quality care system has 9 chapters and follows the division of the INK model as is outlined below: 1) Leadership 2) Staff 3) Strategy and management 4) Means and cooperation 5) Processes 6) Value of the organisation of the pharmacy for the fellow-workers 7) Value of the organisation of the pharmacy for the patients 8) Value of the organisation of the pharmacy for society (caregivers, healthcare insurance companies, suppliers, socially acceptable enterprising). 9) Value of the organisation of the pharmacy for the owner(s)

Country	**Norway**
Dated	25/04/2008
Contact	Trygve Fjeldstad
Email	Trygve.fjeldstad@apotek.no
Source	The Norwegian Pharmacy Association
Weblinks	http://www.apotek.no/sw21108.asp
Summary of data available	In Norway we have introduced national guidelines for Good Pharmacy Practice based on the FIP/WHO document. Our first step was to develop common Nordic guidelines for GPP for the four Nordic countries (Denmark, Norway, Sweden, Finland) (2001) Based on these common guidelines we implemented adjusted national guidelines for Norway (Standards for Pharmacy Practice.) (2003) Our national Norwegian guidelines define the core activities for pharmacies as: - prescriptions and requisitions - self-care - rational prescribing and medicine use - promotion of health and prevention of ill-health. Both a Norwegian and an English version of our national guidelines are available on our website www.apotek.no In Norwegian: http://www.apotek.no/sw27069.asp In English: http://www.apotek.no/sw21108.asp A printed version of both the Nordic and the Norwegian guidelines will be sent you by mail. These documents are in Norwegian.

Country	**Panama**
Dated	02/05/2008
Contact	Telva
Email	telvan@hotmail.com
Source	Ex-President of the Panamian Pharmaceutical Association/ President of FFCC
Weblinks	
Summary of data available	

Country	**Paraguay**
Dated	05/05/2008

Contact	Secretariat AQUIMFARP
Email	fedqui@conexion.com.py
Source	Federación de Quimicos del Paraguay
Weblinks	
Summary of data available	The curriculum of the Faculty of Pharmacy includes elements of GPP through the following subjects: Pharmaceutical Technology, Pharmaceutical Legislation and Deontology, Quality Management in pharmacy related fields. Moreover, the SAIDI-Paraguay programme proposes to train and certify pharmacists on GPP. Also, the Paraguayan Pharmacists Association sent a proposal to the Ministry of Health and Welfare regarding the accreditation of pharmacists based on GPP. At a different level, we also organised training courses on Pharmaceutical Care in which the concepts of GPP were also introduced. GPP guidelines in Spanish

Country	**Philippines**
Dated	02/05/2008
Contact	Normita D. Leyesa
Email	philpharm@surfshop.net.ph
Source	Philippine Pharmacists Association
Weblinks	
Summary of data available	Received national GPP standards for community and hospital pharmacy. Guidelines cover 8 areas (Ethical practice, Work environment, Procurement, Storage and warehousing, Compounding, Dispensing, Monitoring of use and Professional development)

Country	**Portugal**
Dated	18/04/2008
Contact	Joana Viveiro
Email	joanaviveiro@ordemfarmaceuticos.pt
Source	Ordem dos Farmacêuticos/ Portuguese Pharmaceutical Society
Weblinks	
Summary of data available	The Portuguese Pharmaceutical Society published the Good Pharmacy Practice in Hospital Pharmacy and collaborated in the publication of the Good Pharmacy Practice in Community Pharmacy. Unfortunately we just have these GPPs in our mother language (Portuguese). There is an internet link for the Good Pharmacy Practice in Community Pharmacy: http://e-formacao.anf.pt/courses/BPFPt1106/Livro_Azul.pdf

Country	**Republic of Srpska**
Dated	29/04/2008
Contact	Rada Amidzic
Email	farmacia@teol.net
Source	Pharmaceutical Society of the Republic of Srpska
Weblinks	
Summary of data available	The Pharmaceutical Society of the Republic of Srpska is a young association, it was formed in 1996. We have the national guidelines (Guide for Good Pharmacy Practice) which includes recommendations for: promotion of health, the supply of medicines, patient self care etc. This document was established in our country in 1999. 1st revision of this document was in March 2003. The sponsor of this project was WHO and Task Force. The members of our association who were educated then, have been training other members ever since. The Organization Task Force for GPP from Sarajevo does not exist anymore. This document is not avaliable in electronic files. Now we are working on a new revision of the Guide for GPP. The main part of this Guide should be to include advice for patients in Pharmacies.

Country	**Serbia**
Dated	29/04/2008
Contact	Dragana Sovtic
Email	pharmkom@verat.net
Source	Pharmaceutical chamber of Serbia
Weblinks	
Summary of data available	Pharmaceutical chamber of Serbia finished the document for Good Pharmacy Practice in community and hospital pharmacy in January 2008. In March 2008 we sent this document to our Ministry of health, because they have jurisdiction in adopting this document. At present we are awaiting the answer and after that GPP will be an official document and after that we will send it to you.

Country	**Singapore**
Dated	29/04/2008
Contact	Cheng Tiang NG
Email	ng.chengtiang@gmail.com
Source	Pharmaceutical society of Singapore
Weblinks	www.pss.org.sg
Summary of data available	GPP guidelines published in 1997. Formerly known as the Guidelines on Good Dispensing Practice for Pharmacists, these guidelines have been revised and renamed Guidelines for Good Pharmacy Practice with additions on pharmaceutical care, sales of medicines, health promotion and relevant practice issues.

Country	**South Africa**
Dated	18/04/2008
Contact	
Email	
Source	South African Pharmacy Council
Weblinks	http://www.pharmcouncil.co.za/documents/GPP%20in%20South%20Africa%20(2005).pdf
Summary of data available	GPP guidelines, second edition 2004

Country	**Spain**
Dated	21/04/2008
Contact	Consejo General de Farmacéuticos
Email	congral@redfarma.org
Source	Spanish pharmaceutical association
Weblinks	
Summary of data available	The commitment to quality is one of the features that characterise the pharmaceutical profession. Therefore, one of the professional ideas set forth by the Spanish Pharmaceutical Organisation is the implementation of Quality Management Systems through the start up of the Complete Quality Plan by the General Council of Pharmacists of Spain (GCPS). In this way and through the corresponding National Pharmacy Departments, work is being carried out in the Pharmacy Office area for Clinical Analysis, Optical work and Hospital Pharmacy. In the community pharmacies field, the purpose of the Plan is to establish some basic parameters to be used in all the community pharmacies in Spain as a stamp of guarantee that allows the pharmacists to develop manage and provide some top quality pharmacy services that ensure top quality pharmaceutical care for the users of their community pharmacies. With this aim, a “Quality Standard for the Community Pharmacy” has been registered and coming soon it will be published, based on the UNE-EN-ISO 9001:2000 regulation and in which the all the legal and compulsory regulations, both from the State and from the Autonomous Communities on the subject of pharmacy are brought together, as well as the “Quality in Pharmacy” framework by the GCPS. Furthermore, documents

	complementing this regulation for the implementation of the QMS in the community pharmacies have been prepared, containing: A Quality Manual, describing the requirements established by the reference quality regulation. Operating procedures and Technical instructions, in which the processes characterising the pharmacy activity are described. Registers, which record how the functions defined in the procedures and instructions, have been performed. For the Implementation and Certification the community pharmacy may apply and adapt the documentary system offered, either using the help of a consultancy firm or not. Subsequently, in order to be able to obtain the "Quality in Pharmacy" trademark, the QMS implemented in the pharmacy office must be evaluated by the certifying body authorised by the GCPS, to ensure that it really fulfils the demands of the "Quality Standard for the Community Pharmacy". The same methodology will be taken for the implementation of the QMS in the hospital pharmacy. Now, the General Council is working in the "Quality Standard for the Hospital Pharmacy
Country	**Sweden**
Dated	29/04/09
Contact	Astrid Kågedal
Email	astrid.kagedal@apoteket.se
Source	Apoteket AB Sweden
Weblinks	
Summary of data available	We have a Total Quality Management (TQM) concept where the Main processes, the Management processes and the Supportive processes are defined. The Main processes are . "Dispensing Prescriptions" and "Selling Non-Prescription Medicines". The "main processes" are divided into "under processes" and the objective is that all customers should get high quality service every time at every pharmacy and most of the GPP concepts are taken care of. We also use the concept of Continuous Improvements. Staff members can go into the intranet and suggest improvements and then follow their suggestion to see how it is taken care of. The main processes have each a full time pharmacist in a central position with the objective to take care of suggestions and also be responsible for all kinds of development. When a change is decided the processes are changed and there is an implementation routine. The changes are of course communicated. The pharmacies in Sweden are inspected on a regular basis, reports are made from every inspection and a plan has to be elaborated on how to improve.
Country	**United Kingdom**
Dated	18/04/2008
Contact	Yvonne Dennington
Email	yvonne.dennington@rpsgb.org
Source	The Royal Pharmaceutical Society of Great Britain
Weblinks	
Summary of data available	1. Code of Ethics for Pharmacists and Pharmacy Technicians http://www.rpsgb.org/pdfs/coeppt.pdf 2. Professional Standards and Guidance Documents http://www.rpsgb.org/protectingthepublic/ethics/ 3. Medicines, Ethics and Practice Document http://www.rpsgb.org/informationresources/downloadsocietypublications/#m
Country	**Uruguay**
Dated	11/04/2008
Contact	Marta Morkevicius
Email	marta.morkevicius@adinet.com.uy
Source	Pharmaceutical association in Uruguay
Weblinks	

Summary of data available	In Uruguay we have established national standards that are available at our webpage www.aqfu.org.uy. “Buenas Prácticas de Farmacia”,some of them are in English: (1. Good dispensing practice 2. Pharmaceutical care 3. Self medication 4. Rational use of medicines)
Country	**Vietnam**
Dated	21/04/2008
Contact	Xuan Hung
Email	xuanhung29@vnn.vn
Source	Vietnam pharmaceutical association
Weblinks	
Summary of data available	In Vietnam, based on the FIP-WHO guideline, 4 years ago we prepared a draft of GPP standards and published it for comments. In 24-1-2007, at last, the Guideline on GPP standards was approved by our Minister of Health. Until now near 100 pharmacies are accredited (received GPP certificates) by MOH.

附錄 2：FIP Basel 對 GPP 的諮詢

The following main key issues were discussed and expanded upon during the FIP expert consultation on standards in quality of pharmacy services, held during the 69th FIP Congress in Basel 2008.

Areas related to the GPP standards:

- ✓ There is a need to focus on self-care issues. Pharmacists helping people to use and comply with their medicines, whether prescription or non-prescription- "advising on use of medicines for best outcomes".
- ✓ There is a need to incorporate aspects of leadership and management – encouraging mentoring and collaborating with colleagues
- ✓ There is a need to identify a framework that can be broken down in steps and where roles and responsibilities can be identified for each step of a process (e.g. from simple to complex levels).
- ✓ There is a need for clear indicators and measurements for both supply chain and clinical activities
- ✓ Monitoring the "right things." Defining inappropriate indicators for standard setting or accreditation practice may skew practice inadvertently
- ✓ Challenge of measurement – defining outcomes for both major components of practice and establishing standards, indicators and measures can be a very challenging task
- ✓ Inter-professional collaborative practice in the health care team, incorporating concepts of practice such as "Comprehensive Pharmaceutical Care," and "Medication Therapy Management Services (MTMS)" also known as Medicines Management.
- ✓ Antibiotic stewardship is a global concern. This relates closely to rational use of medicines.
- ✓ Managerial role of pharmacists, including skill sets relating to good leadership and mentorship, especially in the need for task-shifting in some settings
- ✓ Issues relating to information on drug pricing and access to medicines
- ✓ GPP standards need to address the availability of essential medicines
- ✓ There is a need to focus on the development of new technologies in pharmacy practice. With new technology there is a need to ensure quality control.

Discussion on using a step-wise approach for GPP implementation:

- ➢ Supported in general; however further work needs to be done to produce broad principles and standards first. More detailed, country specific guidelines or practical handbooks can then be used to assist in implementation. A proposal was made to break down the scope of pharmacy
- ➢ service process into parts –ask the right Questions, give the right Advice and provide the right Treatment (QAT).
- ➢ May include aspirational goals that should be relevant to all (including developing countries) recognizing that not all of them will be achievable. Using a measurement tool to assess differences in 'real life' from 'aspired practice' should allow for organisations/practitioners to assess where they sit on the "evolutionary ladder" of implementing GPP.
- ➢ Given the spectrum across which different sizes and types of pharmacies, a "GPP grading system" does not need to be linear but can incorporate the scope, the level of quality and assurance of each component part of a pharmacy. The range and quality of pharmaceutical services may be very different but should be measurable.
- ➢ Should be formulated on evidence-based practice – research and experience from pilots – discussion about definition of evidence followed and need to incorporate/capture examples of good practice that are not traditional Randomized Control Trials (RCT)s .
- ➢ Global framework must be relevant to developing countries – and should aim to set aspirational

standards for the profession globally – bearing in mind that one size will fit all

- GPP Quality management should look into setting scope of practice, levels of competence and assurance of quality services

Quality Assurance systems:

- Concerns with inclusion/implementation of ISO/American systems into pharmacies in Portugal (only 5% certified) and in Finland. There is a fear about setting standards too high and too far from pharmacy practice. A need for reality checks. Based on sound principles of GPP, developing countries need to adapt existing international standards to their specific needs and conditions of the region/country.
- Need to set up quality assurance as a step-wise process encouraging continuous improvement. Example basic level = there are pharmacists and medicines; next step = providing information; next step= having patient records available for clinical management ; finally, with a pro-active engagement of the pharmacist in managing treatment therapy
- The need to assure quality of pharmaceutical products throughout the distribution chain with particular attention to the current prevalence of substandard and counterfeit products in some national markets. This includes sales of medicines by persons who are not authorized.

Education and CPD:

- Quality of education and training both as initial practitioners and for continuing professional development should be included in guidelines.
- The roles, responsibilities and accountability of all key stakeholders, such as institutes, schools, pharmaceutical associations…etc need to be defined in the context of implementing an agreed framework of continuing professional development.
- Reinforce that there is a lack of training of interdisciplinary teams (e.g. physicians, nurses and pharmacists being educated and trained together)
- Need for curricular reform to close the gap for what we currently know to be competent in practice
- Requirement to re-train – need continuing professional development
- Strengthening the need for more comprehensive pharmaceutical workforce planning, especially in capacity building for education and training institutions for pharmacists, technicians and other pharmacy cadres. This may require a curricular reform of all levels of the workforce.

Implementation of GPP:

- Need for step-wise progression over time
- GPP Standard had the greatest impact when compared to other FIP documents in Portugal – 98% of pharmacies comply with GPP.
- Need to know about the difficulties faced in different countries and how these can be addressed. Example of difficulty faced is the lack of coordination between the different groups/agencies involved in provision of medicines – need to coordinate these agencies. Also need to recognize that although pharmacists give advice, many patients may not go through the standard system and do not receive advice. Need to think about how to manage and coordinate and relate to people at the country level.
- Need topic specific guidelines that are healthcare system specific. For example, GPP also require physicians and other medical personal to understand, respect and be involved in the process implementation of GPP, as part of their everyday work. National pharmaceutical associations need to collaborate with their counterparts in the medical associations and other health professions when implementing GPP.
- Setting measurable indicators for monitoring and evaluating the implementation of the guidelines. What is the role of the FIP member organizations and regional forums as key stakeholders?

名詞解釋 Glossary

Term	Definition as used in this document only
National Standards	The standards, guidelines, recommendations and other pronouncements of professional organizations of pharmacy and in some countries, these are laws, regulations, standards, ordinances or other requirements enacted or promulgated by an official body at any level of government
Good Pharmacy Practice	The practice of pharmacy that responds to the needs of the people who use the pharmacists' services by providing optimal, evidence-based care. To support this practice it is essential that there be an established national framework of quality standards and guidelines.
Pharmaceutical care	A patient centered practice in which the practitioner assumes responsibility for a patient's drug related needs and is held accountable for this commitment.
Medical product	For the purpose of this document, this includes, at least, medicines, medical devices and their accessories, active pharmaceutical ingredients and excipients which may be used in health care delivery, self-medication and/or clinical research, as defined in national legislation.
Pharmacists	Health care professionals whose professional responsibilities include seeking to ensure that people derive maximum therapeutic benefit from their treatments with medicines. This requires them to keep abreast of developments in pharmacy practice and the pharmaceutical sciences, professional standards requirements, the laws governing pharmacy and medicines and advances in knowledge and technology relating to use of medicines.
Qualified Pharmacy Technician/Dispensary Assistant	A person with formal dispensing training involved only in the dispensing of medicines. The training of this person would have taken place at a recognised training institution and a certificate or license would have been issued.
Unqualified Pharmacy Technician/Dispensary Assistant	A person who is involved in the dispensing of medicine, but who has only received "on the job" or "in house" training.
Community Health Care Worker	A person who is trained to provide simple, low level health care commensurate with the level of training
Continuous Quality Improvement	An internally driven management strategy and approach that aims to constantly improve quality by: identifying current and future desired outcomes; adopting relatively continuous assessments and evaluations of performance and achievement; identifying potential causes of quality defects; taking appropriate action to avoid or correct deficiencies; implementing process improvements and innovations; and evaluating the impact of all interventions.
Competence	The ability to perform one's duties accurately and confidently, make correct judgments, and interact appropriately with patients and with colleagues.

	Professional competence is characterized by good problem-solving and decision-making abilities, a strong knowledge base, and the ability to apply knowledge and experience to diverse patient-care situations.
Competencies	The knowledge, skills, behaviours and attitudes that an individual accumulates, develops, and acquires through education, training, and work experience.
Continuing Education	A structured process of education designed or intended to support the continuous development of pharmacists to maintain and enhance their professional competence.
Continuing Professional Development	The responsibility of individual pharmacists for systematic maintenance, development and broadening of knowledge, skills and attitudes, to ensure continuing competence as a professional throughout their careers
Scope of practice	The range of professional tasks and functions that a practitioner can perform as specified by legislation, rules, or regulations; the boundaries within which a practitioner may practice.

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