

REVISED FIP BASEL STATEMENTS ON THE FUTURE OF HOSPITAL PHARMACY

國際藥學聯合會（FIP）關於醫院藥學未來發展的巴塞爾聲明（Basel Statement）修訂版

Since the original Basel Statements on the Future of Hospital Pharmacy were released in 2008, the Statements have been used worldwide to guide the development of practice in hospital pharmacy. This revision was developed by the FIP Hospital Pharmacy Section in 2014, and was approved Bangkok, Thailand in September 2014. The final revised Statements were released on 10th September 2015. For more information about the Basel Statements, the FIP Hospital Pharmacy Section and FIP, please see <http://www.fip.org/basel-statements>.

關於醫院藥學未來發展的巴塞爾聲明自2008年發布以來，已廣泛被世界各國採用為引導醫院藥學發展的準則。國際藥學聯合會（FIP）醫院藥學組再度於2014年修訂巴塞爾聲明，並於同年9月在泰國曼谷召開的國際藥學大會上獲得批准。最終修訂版已於2015年9月10日發布。如需了解有關巴塞爾聲明、國際藥學聯合會醫院藥學組、以及國際藥學聯合會的更多訊息，請連結：

<http://www.fip.org/basel-statements>。

Overarching and Governance Statements

總則

1. The overarching goal of hospital pharmacists is to optimize patient outcomes through collaborative, inter-professional, responsible use of medicines¹ and medical devices.

1. 醫院藥師的終極目標是經由跨領域合作和盡責的使用藥物、醫療器材等方式，使病人得到最佳的治療結果。

The responsible use of medicines means:

“盡責的使用藥物”是指：

- That a medicine is only used when necessary and that the choice of medicine is appropriate based on what is proven by scientific and/or clinical evidence to be most effective and least likely to cause harm. This choice also considers patient preferences and makes the best use of limited healthcare resources.

藥物的使用，只有在必要的時候，且其選擇必須建立在經科學和/或臨床證據證明其效果最佳、副作用最小的基礎上。這種選擇還需要考慮患者意願，並能使有限的醫療資源得到最佳利用。

- There is timely access to and the availability of quality medicine that is properly administered and monitored for effectiveness and safety.

能及時獲取，並可以監測其有效性和安全性的確保品質的藥品。

- A multidisciplinary collaborative approach is used that includes patients and those in addition to health professionals assisting in their care.

多元化跨領域合作的方式，是納入病人、健康專業工作者、以及其他提供幫助的人員。

2. At a global level, evidence-based hospital pharmacy practice standards should be developed. These should assist national efforts to define standards for the extent and scope of hospital pharmacy services and should include corresponding human resource and training requirements.

2. 應在全球層面，制定具實證的醫院藥學作業規範。這將幫助不同國家來確定其醫院藥學服務的廣度與深度標準，還應包括相對的人力資源和訓練需求。

3. Hospital pharmacists should engage health authorities and hospital administrators to ensure appropriate resources for, and design of, the hospital medicines-use process.

3. 醫院藥師應參與衛生行政主管部門及醫院管理部門的工作，以確保醫院藥品使用流程得到適當的資源和合理的設計。

4. Health authorities should ensure that each hospital is serviced by a pharmacy that is supervised by pharmacists who have completed advanced training in hospital pharmacy.

4. 衛生行政主管部門應確保每個醫院都應該有一個由藥師管理的藥學部門，且藥師們都應完成醫院藥學的進階訓練。

5. The Chief Pharmacist/Director of Pharmacy should be the accountable professional coordinating the responsible use of medicines¹ in the hospital.

5. 醫院藥學部門主管/主任應該是負責協調醫院內藥物盡責使用的專業負責人。

6. Hospital pharmacists should serve as a resource regarding all aspects of medicines use and be accessible as a point of contact for patients and health care providers.

6. 醫院藥師應成為病人與其他醫務人員聯繫有關藥物使用相關問題的窗口。

7. All prescriptions should be reviewed, interpreted, and validated by a hospital pharmacist prior to the medicine being dispensed and administered.

7. 所有處方，都必須由醫院藥師審核、解讀和認可之後，才能調配及給藥。

8. Hospital pharmacists should monitor patients taking medicines to assure patient safety, appropriate medicine use, and optimal outcomes for inpatients and outpatients. When resource limitations do not permit pharmacist monitoring of all patients taking medicines, patient-selection criteria should be established to guide pharmacist monitoring.

8. 醫院藥師應對住院及門診病人的用藥進行監測，以確保病人能安全、正確的使用藥物，達到最佳治療效果。如果因資源有限，致使藥師無法追蹤監測所有病人，則應制定病人選擇標準來指導藥師選擇用藥監測對象。

9. Hospital pharmacists should be allowed to access and document in the full patient record.

9. 應給予醫院藥師查看完整病歷並紀錄的權限。

10. Hospital pharmacists should ensure that patients or care givers are educated and provided written information on the appropriate use of medicines.

10. 醫院藥師需對病人或其照護者進行用藥教育，並提供書面用藥指導資料。

11. Hospital pharmacists should provide orientation, drug information and education to nurses, physicians, and other hospital staff regarding best practices for medicines use (a best practice is a method or technique that has consistently shown results superior to those achieved with other means, and that is used as a benchmark).

11. 醫院藥師應為護理、醫師、和其他醫技人員提供關於藥物之最佳實踐資訊和教育訓練（最佳實踐是指與其他方法相比，能持續顯示出更優效果的方法或技術，且已經成為標竿）。

12. Undergraduate pharmacy curricula should include hospital-relevant content, and post-graduate training programs and specializations in hospital pharmacy should be developed.

12. 學校藥學教育課程應納入醫院藥學相關內容，並應發展設置醫院藥學畢業後教育訓練課程和專科培訓制度。

13. Hospital pharmacists should actively engage in research into new methods and systems to improve the use of medicines and of human resource needs in hospital pharmacy.

13. 醫院藥師應積極參與新方法和新系統的研究，進而優化醫院藥學部門的藥物使用和人力資源配置。

14. Hospital pharmacists should take responsibility for the management and disposal of waste related to the medicine use process, and advise on disposal of human waste from patients receiving medicines.

14. 醫院藥師應負責管理和處置與藥物使用過程相關廢棄物，並對病人因用藥所致之廢棄物處理提供指導。

15. Hospital pharmacists should take responsibility for all aspects of selection, implementation and maintenance of technologies that support the medicine use process, including distribution devices, administration devices and other equipment.

15. 醫院藥師應負責藥品使用過程中各種技術的選擇、使用和維護等環節，包括調配設備、給藥裝置，以及其他設備。

16. Hospital pharmacists must ensure proper storage to maintain the integrity of medicines across the supply chain to ensure quality, safety and security.

16. 醫院藥師必須確保藥品在整個供應鏈中獲得適當的儲存，能確保藥品的品質、安全，與防竊。

17. Hospital pharmacists should ensure appropriate assessment, development, implementation and maintenance of clinical decision support systems and informatics that guide therapeutic decision making and improve the medicine use process.

17. 醫院藥師應確保臨床決策系統的適當性評估、開發、和維護，以引導治療決策及優化藥品使用過程。

18. Each pharmacy should have contingency plans for medicine shortages and emergencies

18. 每個藥學部門都應建立藥品短缺和突發事件的應變方案。

19. The “seven rights” (right patient, medicine, dose, route, information, documentation and time) should be fulfilled in all medicine-related activities in the hospital.

19. 醫院內所有與藥品使用有關的環節都應當遵循“七個正確”原則（正確的患者、正確的藥品、正確的劑量、正確的給藥途徑、正確的藥物資訊、正確的存檔記錄、以及正確的用藥時間）。

Theme 1 – Procurement

主題 1——醫院藥師與採購

20. Hospital pharmacists should be involved in the complex process of procurement of medicines and health products, promoting equity and access. They should ensure transparent procurement processes are in place in line with best practice and national legislation, are free from conflict of interest, and are based on the principles of safety, quality and efficacy.

20. 醫院藥師應參與藥品和醫療用品的採購過程中，以促進公平性和可及性。藥師應遵循安全、優質和有效的原則，確保採購流程公開透明，符合最佳實踐和國家法律，並且沒有利益衝突。

21. Procurement practices must be supported by strong quality assurance principles, regularly reviewed and adapted to fit different settings and emerging needs in the most appropriate and cost effective way.

21. 採購過程必須有強大且保證品質的系統支持，並定期檢討調整，使其能滿足不同醫療場所或突發事件的需求，並保持最適當與最佳成本效益比。

22. Procurement should not occur in isolation, but rather be guided by the formulary selection process. This includes the procurement of standard concentrations of high-risk medicines including electrolytes.

22. 藥品採購不應單獨進行，而應受處方集遴選程序指導，包括標準濃度的高危險藥品的採購（如電解質溶液）。

23. Procurement must be supported by a reliable information system that provides accurate, timely, and accessible information.

23. 藥品採購必須有可靠的訊息系統支持，以獲得準確、及時和便捷的資訊。

Theme 2 - Influences on Prescribing

主題2——醫院藥師對處方的影響

24. Hospitals should utilize a medicine formulary system (local, regional, and/or national) linked to standard treatment guidelines, protocols, and treatment pathways based on the best available evidence.

24. 醫院應使用與標準治療指南、方案和治療路徑相符，且具有最優證據的藥品處方集系統（地方性、地區性和/或全國性的）。

25. Hospital pharmacists should be key members of pharmacy and therapeutics committees to oversee all medicines management policies and procedures, including those related to off-label use and investigational medicines.

25. 醫院藥師應作為藥事管理與藥物治療委員會的核心成員，負責審查所有藥品管理政策和規定，包括非法定適應症用藥和臨床試驗用藥方面。

26. Hospital pharmacists should have a key role in educating prescribers at all levels of training on the access to and evidence for responsible use of medicines, including the required monitoring parameters and subsequent prescribing adjustments.

26. 醫院藥師應在對處方者各個層次的教育訓練上扮演關鍵角色，使他們能掌握藥物盡責使用的原則和證據，包括必要的指標監測和相應的處方調整。

27. Hospital pharmacists should be an integral part of the multidisciplinary team responsible for therapeutic decision making in all patient care areas.

27. 醫院藥師應是負責病人治療決策的多元跨科團隊中的必要成員。

28. Hospital pharmacists should promote seamless care by contributing to the transfer of information about medicines whenever patients move between and within health care settings.

28. 無論病人在不同醫療機構之間或在同一醫療機構內部轉移，醫院藥師都應該及時交接患者用藥訊息，使病人能獲得無縫的藥事照護。

29. Appropriately trained and credentialed hospital pharmacists should participate in collaborative prescribing.

29. 接受過適當訓練並獲得相關任命或授權的藥師應參與合作開立處方。

Theme 3 - Preparation and Delivery

主題3——醫院藥師與藥品配製和配送

30. Hospital pharmacists should assume responsibility for storage, preparation, dispensing, and distribution of all medicines, including investigational medicines.

30. 醫院藥師應負責所有藥品，包括臨床試驗用藥品的儲存、配製、調劑和發放。

31. Hospital pharmacists should assume responsibility for the appropriate labeling and control of medicines stored throughout the facility.

31. 醫院藥師應負責所有藥品正確標示和醫院內藥物的儲存與管控。

32. Hospital pharmacists should be involved in determining which medicines are included in ward stock and standardizing the storage and handling of ward medicines.

32. 醫院藥師應參與病房常備藥的品項與數量的決策，並規範這些藥品的儲存和管理。

33. Hospital pharmacists should ensure that compounded medicines are consistently prepared to comply with quality standards. This includes taking responsibility for ensuring medicines not commercially available in a suitable formulation are prepared to accepted practice standards, and ensuring that injectable admixture services comply with accepted practice standards.

33. 醫院藥師應確保調製藥品的配製過程具一致性且符合品質標準，包括：必須確保無市售符合配製標準的藥品，並確保注射用調製藥品的混合配製過程符合公認的操作標準。

34. The preparation of hazardous medicines including cytotoxics should be under the responsibility of the hospital pharmacist and prepared under environmental conditions that minimize the risk of contaminating the product and environment, as well as minimizing exposure of hospital personnel to harm using accepted practice standards.

34. 高危藥品（包括細胞毒性藥品）的配製必須由醫院藥師在適當的環境條件下進行，並且需符合相關標準，以使藥品與環境污染和醫院員工藥品暴露的風險降至最低。

35. Hospital pharmacists should implement evidence-based systems or technologies (e.g., automated prescription-filling, unit dose distribution, machine-readable coding systems, etc.) to decrease the risk of medication errors.

35. 醫院藥師應使用有實證支持的系統或技術（如自動化處方調配、單一劑量給藥和機器讀碼系統等）來降低給藥錯誤的風險。

36. Hospital pharmacists should support the development of policies regarding the use of medicines brought into the hospital by patients, including the evaluation of appropriateness of complementary and alternative medicines.

36. 醫院藥師應支持建立病人自備藥的政策，包括評估補充和替代藥品。

37. Hospital pharmacists should implement systems for tracing medicines dispensed by the pharmacy (e.g., to facilitate recalls, etc.).

37. 醫院藥師應建立已調配發放藥品的追蹤系統（例如藥品召回等）。

38. Concentrated electrolyte products (such as potassium chloride and sodium chloride) and other institutionally-identified high-risk medicines should be dispensed in ready-to-administer dilutions, and stored in secure, separate areas with distinct labels.

38. 濃縮的電解質藥品（如氯化鉀和氯化鈉）以及其他高危藥品必須稀釋至可直接使用的溶液形式後方能發放，並應存放在具有醒目的標籤標記的安全、隔離區域。

39. Hospital pharmacists should develop simple, rules-based approaches to advancing patient safety; for example, when a large number of dosage units are needed to give a dose (more than two tablets, vials, etc.), the prescription should be verified prior to preparation or dispensing.

39. 醫院藥師應制定簡單、標準化的操作程序來促進病人用藥安全。例如，單次劑量較大時（如單次給藥量超過兩顆、兩瓶等），在調配或發藥之前必須先確認。

Theme 4 – Administration

主題4——醫院藥師與給藥

40. Hospital pharmacists should ensure that the information resources needed for safe medicines preparation and administration are accessible at the point of care.

40. 醫院藥師應確保在任何提供病人照護的場所，能夠隨時獲得藥物安全調配和給藥所需的資訊。

41. Hospital pharmacists should ensure that clinically relevant allergies, drug interactions, contraindications, past adverse events and other relevant medication history details are accurately recorded in a standard location in patient records and evaluated prior to medicine use.

41. 醫院藥師應確保所有臨床相關的過敏情況、藥物相互作用、禁忌症、過去藥物不良事件，以及其他用藥史等，都會在病歷中規定的位置準確的記錄，且在給藥前都有評估相關紀錄。

42. Hospital pharmacists should ensure that medicines are packaged and labeled to ensure identification and to maintain integrity until immediately prior to administration to the individual patient.

42. 醫院藥師應確保藥品有包裝和標籤，以確保給藥前，能辨識個別病人的藥品且保持包裝完整。

43. Medication labels should be clear and have sufficient information to ensure safe administration, including at least 2 patient identifiers, the name of the medicine, prescribed route, dose in mass and, where appropriate, volume and rate of administration.

43. 藥品標籤應清晰、內容足以確保給藥安全。標籤的內容應包含：至少 2 種病人辨識方式、藥品名稱、給藥途徑、給藥劑量，或藥品的給藥速率及體積。

44. Hospital pharmacists should ensure that health care professionals who administer medicines are appropriately trained in their use, hazards, and necessary precautions.

44. 醫院藥師應確保給藥的醫療人員接受過藥物使用、危險性及注意事項等方面的適當訓練。

45. Doses of chemotherapy and other institutionally-identified high-risk medicines should be independently checked against the original prescription by at least two health care professionals, 1 of whom should be a pharmacist, prior to administration.

45. 在化療藥和其它高危險藥品給藥前，至少應有兩名醫療人員（其中一名應是藥師）分別核對原始處方。

46. Hospital pharmacists should develop and implement policies and practices that prevent route errors. Examples include:

46. 醫院藥師應制定並實施防止給藥途徑錯誤的相關政策和規範。例如：

- Labeling of intravenous tubing near insertion site to prevent misconnections;
在靜脈輸液管進針處加上標示，以防止連接錯誤；
- Use of enteral feeding catheters that cannot be connected with intravenous or other parenteral lines;
使用無法與輸液管或其他管路相連的腸內營養管；
- Packaging vinca alkaloids to prevent inadvertent intrathecal administration;
將長春鹼類藥物進行特殊包裝，以防止不小心誤為鞘內給藥；
- Use of oral syringes that are distinctly different from hypodermic syringes to prevent injection of enteral or oral medicines.
口服用的針筒應明顯區別於皮下注射器，以防止把腸道給藥或者口服藥品用於皮下注射。

47. Hospital pharmacists should ensure the development of quality assurance strategies for medicines administration to detect errors and identify priorities for improvement.

47. 醫院藥師應負責制定用藥的品質保證策略，以發現用藥錯誤，並確認改善重點及優先順序。

48. The medicines administration process should be designed such that transcription steps between the original prescription and the medicines administration record are eliminated.

48.給藥流程的設計，必須取消原始處方和給藥記錄間的處方轉抄步驟，以避免錯誤。

Theme 5 - Monitoring of Medicines Use

主題5——用藥監測

49. An easily accessible reporting system for defective medicines should be established and maintained. Reports of defective or substandard medicines should be reviewed internally and sent in a timely manner to regional or national pharmacovigilance or regulatory reporting programs, and the manufacturer.

49. 應建立並維護品質不良或療效不佳藥品的通報系統。對於不良或療效不佳藥品，應先進行內部評估，並及時上報地區或全國藥物警示、管理通報系統和生產廠商。

50. An easily accessible reporting system for adverse drug reactions should be established and maintained. Reports of reactions should be reviewed internally and sent in a timely manner to regional or national pharmacovigilance or regulatory reporting programs. These data should be regularly reviewed to improve the quality and safety of medicines use practices.

50. 應建立並維護藥品不良反應通報系統。將不良反應的情況進行內部評估，並及時上報地區或全國藥物不良反應中心。並應定期檢查相關資料，以確保藥物使用的質量和安全。

51. An easily accessible, non-punitive reporting system for medication errors, including near misses, should be established and maintained. Reports of medication errors should be reviewed internally and sent to regional or national medication error reporting or regulatory programs. These data should be regularly reviewed to improve the quality and safety of medicines use practices.

51. 應建立並維護便捷、非懲罰性的用藥錯誤（包括幾近錯誤事件）通報系統，將用藥錯誤事件進行內部評估，並上報地區或全國藥物錯誤通報系統。並應定期回顧以上資料，以確保藥物使用的質量和安全。

52. Medicines use practices should be self assessed and compared with benchmarks and best practices to improve safety, clinical effectiveness, and cost-effectiveness.

52. 應對醫院藥品的使用情況進行自我評估，透過與標竿或最佳作業模式的比較，來提升用藥安全、臨床有效性和成本效益比。

53. The medicines use process should be reviewed through an external accreditation or quality improvement program. Hospitals should act on reports to improve the quality and safety of their practices.

53. 應對醫院藥品使用的流程通過外部評鑑或品質提升計劃來進行檢查，並據以改善作業流程、提高質量安全。

54. Pharmacists' clinically-relevant activities should be documented, collected and analyzed to improve the quality and safety of medicines use and patient outcomes. Activities which significantly impact individual patient care should be documented in the patient record.

54. 應對藥師的臨床相關活動進行記錄、收集和分析，以改善用藥品質、安全和病人藥物治療成效。對病人藥物治療成效有顯著影響的臨床介入，應記載於病歷中。

55. Systematic approaches (e.g., trigger tools) should be used to provide quantitative data on adverse drug events and optimal medicines use. These data should be regularly reviewed to improve the quality and safety of medicines practices.

55. 應該使用系統性的方法（例如預警工具）來提供醫院內藥物不良事件與合理用藥的量化數據。應對以上數據進行定期評估以改善醫療的質量和安全。

Theme 6 - Human Resources, Training and Development

主題6——醫院藥師人力資源配置、培訓和發展

56. At a national level, competency frameworks are defined, established and regularly assessed.

56. 應在國家層級定義、建立，並定期評估藥師的職業資質評價體系。

57. At a national level, hospital pharmacists should engage health authorities to bring together stakeholders to collaboratively develop evidence-based hospital pharmacy human resource plans, to support responsible use of medicines including those in rural and remote areas.

57. 在國家層級，醫院藥師應與衛生行政主管部門密切合作，召集所有利益相關方，共同制定循證的醫院藥學人力資源規劃，在所有地區（包括農村及偏遠地區）推行盡責的藥物使用。

58. Hospital pharmacists should work with key stakeholders to ensure that workforce education, training, competency, size, and capacity are appropriate to the scope of services, coverage, and responsibilities of all cadres providing pharmacy services.

58. 醫院藥師應與關鍵利益相關方合作，確保藥事人員的教育、培訓、資質、規模及能力等，足以與所需之服務領域、範圍和責任相當。

59. Hospital pharmacy workforce plans should describe strategies for human resource education and training, recruitment and retention, competency development, remuneration and career progression pathways, diversity-sensitive policies, equitable deployment and distribution, management, and roles and responsibilities of stakeholders for implementation.

59. 醫院藥學部門的人力規劃應包括人力資源的教育與培訓、招聘與留任、能力提升、薪酬與職業發展、多元化政策、合理的工作配置與分配、管理以及工作職責等策略。

60. Hospitals should maintain human resource information systems that contain basic data for planning, training, appraising, and supporting the workforce. Data should be collated at a national level to improve workforce planning.

60. 醫院應保有人力資源系統，包括人員配置、培訓、評價和支持的基本數據。以上數據應該在國家層面上進行收集整理，以促進人力資源計劃制訂。

61. The training programs of pharmacy support staff should be nationally formalized, harmonized, and credentialed within a defined scope of practice.

61. 應在國家層級建立範圍明確、正式、統一和經過認證的藥學輔助人員培訓項目。

62. Hospital human resource policies should be founded in ethical principles, equity and human rights, and be compliant with labor regulations, guidelines, and hospital pharmacy practice standards.

62. 醫院的人力資源政策，應符合倫理原則、平等和人權，並應符合相關的勞動法規、指南，以及醫院藥學作業準則。

63. Hospitals should use the nationally accepted competency framework to assess individual human resource training needs and performance.

63. 醫院應使用國家認可的資質評價體系，來評估每個員工的人力資源培訓需求和績效。

64. To promote interprofessional education and team-based care, the role of hospital pharmacists, including collaborative prescribing, should be included in the curriculum of other health care professionals, and the roles of other health care professionals should be included in the pharmacy curricula.

64. 為促進跨專業教育和團隊合作照護模式，醫院藥師的角色，包括合作處方模式，應納入其他醫療團隊的訓練課程中，同時，其他醫療人員的角色，也應納入藥學人員的課程中。

65. Postgraduate clinical courses should be developed to prepare hospital pharmacists for collaborative prescribing of medicines, including instruction in legal and professional accountability.

65. 應設置畢業後臨床教育課程來培養醫院藥師合作處方的能力，包括法律及專業責任方面的課程。

(Simplified Chinese: Translated by Prof. Zhang Chao, Ms. Dong Shu-jie, Mr. Shi Long-wei, Ms. Li Pu. Revised by Prof. Zhu Zhu, Prof. Chen Bing, from Chinese Pharmaceutical Association By September 25, 2015)

(Traditional Chinese: Translated by Chun-Yu, Wang President of Taiwan Society of Health System Pharmacists By September 16, 2016)

Note: the texts marked in yellow indicated those revised or added compared with the Statement in 2008 version.