行政院及所屬各機關出國報告

（出國類別：參加會議）

參加第七屆亞洲藥物流行病學研討會

（7th Asian Conference on Pharmacoepidemiology）

服務機關：行政院衛生署食品藥物管理局
姓名職稱：吳孟修 科長
派赴國家：印度邦加羅爾
出國期間：101 年 10 月 25 日至 10 月 30 日
報告日期：101 年 11 月 30 日

摘　要

第七屆亞洲藥物流行病學研討會（7th Asian Conference on Pharmacoepidemiology）係由國際藥物流行病學學會(ISPE)主辦，於101年10月26日至10月28日在印度邦加羅爾Bengaluru (Bangalore)舉行。本次研討會主題為Medication Safety and Effectiveness：Building Evidence Through Good Pharmacoepidemiology Practice，內容包括藥物安全監視、藥物流行病學、風險與效益評估及管控等。會議首日安排兩種自由選擇參加之教育性工作坊(Pre-Conference Workshop)，後兩日安排大會主題演講(Keynote speeches)、專題講座(Plenary session)及自由選擇參加之專題口頭報告(Contributed paper session)與壁報論文(poster session)發表。職於會中發表口頭論文「Management Strategies for Reducing Hypnotics Consumption in Taiwan」乙篇，透過經驗分享與討論交流，讓各國瞭解我國為維護民眾用藥安全對防範安眠類藥物濫用所採取之管理作為。就會議心得，提出建議事項：一、密切注意歐盟最新藥物安全監視相關法規之進展，精進我國藥物安全監視機制；二、借鏡澳洲藥物風險評估及管理，強化國內用藥品質及安全管理；三、瞭解各國藥物安全監視進展，建立合作與聯繫管道，汲取其經驗，以強化我國藥物安全監視暨風險管理機制。

參加第七屆亞洲藥物流行病學研討會

目　錄

壹、目　的

近來我國安眠藥使用量逐年升高，實地稽核亦發現佐沛眠(Zolpidem)安眠藥濫用情形增加，職於該會議「Medication utilization, expenditure and management」之主題領域下，以「Management Strategies for Reducing Hypnotics Consumption in Taiwan」為題進行口頭報告，藉由此次發表可讓各國瞭解我國為維護民眾用藥安全對防範安眠類藥物濫用所採取之管理作為，並可瞭解各國藥物安全監視政策之發展及相關法規修訂，增進藥物流行病學研究方法的知識。

貳、過　程

參加第七屆亞洲藥物流行病學研討會之行程如下，會議地點為 Sheraton Bangalore Hotel at Brigade Gateway, Bangalore, India。

日期	行程內容
10 月 25 日	啟程，抵達印度邦加羅爾國際機場
10 月 26 日	全天(9:30-17:15) 參加第七屆亞洲藥物流行病學研討會 Pre-Conference Workshop - Advanced topics in Pharmacoepidemiology。
10 月 27 日	全天(7:30-17:30) 參加第七屆亞洲藥物流行病學研討會，晚上(19:30-22:00) 參加晚宴 Gala Dinner。
10 月 28 日	全天(7:30-17:15) 參加第七屆亞洲藥物流行病學研討會，口頭報告「Management Strategies for Reducing Hypnotics Consumption in Taiwan」。
10 月 29 日	搭機返國
10 月 30 日	抵達桃園國際機場

參、心　得

國際藥物流行病學學會(The International Society for Pharmacoepidemiology, ISPE)為致力於促進藥物流行病學發展以增進大眾健康之國際非營利組織，藉由學術界、藥業界之科學家、醫生和藥師等醫藥專業人士參與，分享藥物使用、研究和臨床上對藥物安全性和有效性的經驗，並進行討論，以達到更有效的藥物利用率及更好的藥物風險管理。ISPE 自 2006 年在中國上海舉行第一屆亞洲藥物流行病學研討會（Asian Conference on Pharmacoepidemiology, ACPE）後，每年皆於亞洲舉辦 ACPE，今年第七屆亞洲藥物流行病學研討會係由 ISPE 和印度 Jagadguru Sri Shivaratreeshwara (JSS) University 及 Indian Society for Clinical Research (ISCR)共同主辦。

本次大會邀請台灣、美國、英國、日本、澳洲、中國、瑞典、印度與荷蘭等國共 16 位專家學者演講，來自美國、台灣、印度、日本、韓國、中國、泰國、澳洲、伊朗、斯里蘭卡、沙烏地阿拉伯、俄羅斯等國之流行病學、生物統計學、醫學、護理學、藥理學、藥劑學、法律、衛生經濟學等領域計 200 多名研究人員參加。會議議程首日安排基礎及進階 2 種藥物流行病學教育工作坊(Pre-Conference Workshop)供參加者自由選擇(各 6 場演講)；後 2 日

除各一場大會主題演講外，上午皆有 1.5 小時之專題演講，同一時段皆安排 2 場，每場皆有 3 個子題，專題演講包括：1. 藥物流行病學 2.藥物使用之效益及風險評估 3.藥品效益比較 4.抗生素使用規範 5.藥物安全監視等 5 主題；每天中午有 7 項主題 2 小時之壁報論文展示，每天展出約 60 篇，壁報主題包括：1.藥物流行病學和藥物安全監視方法 2.藥物使用研究 3.上市後藥物有效性和安全性評估 4.藥物安全和風險管理 5.藥源性疾病的預防和治療 6. 基因藥理學和藥物安全 7.用藥規範 8.實證醫學/藥學 9.合理用藥 10.預防用藥錯誤和藥物誤用/濫用 11.罕見的疾病及罕藥 12.藥物流行病學和傳統藥物 13.藥物政策和管理 14.其他相關領域等 14 部分；下午則為專題口頭報告(Contributed paper session) ，計有危險監控及訊息偵測、優良照護品質、老人及幼兒用藥注意事項、藥物使用安全及效用之評估、抗生素使用考量、藥品使用及管理等 7 個主題，每主題 6 人發表，每位發表者進行 15 分鐘口頭報告，職於「藥品使用及管理」之主題下，以「Management Strategies for Reducing Hypnotics Consumption in Taiwan」為題進行口頭報告。本次會議內容相當豐富，以下謹就較為重要單元加以敘述。

一、 優良藥物流行病學

藥物流行病學是近來新興、熱門且重要的研究領域，非僅單與

研究相關，亦為藥物安全監控與衛生單位管理所需，一般可分為三部分：一是找出藥物使用潛在性安全性問題，最常使用的方式是透過自發性藥物不良反應通報系統，偵測藥品潛在性的安全問題。二為利用科學研究來驗證前述的藥物安全性問題，最常使用如，案例對照研究(case-control studies)、世代研究(cohort studies)、隨機性的控制試驗(randomized controlled trials)、登記性研究(registries)、調查報告(surveys)等方法。第三部分則為藥品安全性問題的處理機制，包括透過用藥教育、仿單修改、限制藥品處方與使用等，及建立多元化的溝通管道與方式。如此可以得知藥物使用之效益及風險，進而改善大眾健康。

藉由此部分介紹，可使職及與會者對藥物流行病學有更完整的概念，瞭解藥物流行病學非單是一門學問，而是可以實際運用改善病患藥物安全及用藥品質的實用科學；並可使與會的藥商代表瞭解藥商自發性通報及案例研究之重要性及必要性，使研究者瞭解藥物流行病學是藥品研究重要的一環，使臨床醫師、藥師、護理人員等對藥物不良反應的通報有更進一步的瞭解，讓來自不同背景的與會者為建構更完善之用藥環境共同努力。

二、 優良用藥品質

為使用藥獲得最大效益使傷害最小化，藥物除需經上市前評估和

核准，藥商、藥廠亦須經質量系統認可和許可，以確保藥物品質及安全、有效，另外，藥物上市後監視為現今全球藥物管理重點。因此來自澳洲的講者分享澳洲 Therapeutic Goods Administration (TGA)所訂的國家藥物政策，該國藥物管理政策四個主要目標：1.及時給予國民所需的藥物(含處方藥、非處方藥及醫療器材)和負擔得起的醫藥費用 2.訂定確保藥物品質、安全性及有效性的適當標準 3.確保用藥品質 4.保障有擔當、肯負責的藥事產業，以改善藥物使用品質和國民健康。

用藥品質（the quality use of medicines , QUM）定義為：明智的藥物管理方式、選擇治療疾病和保持健康的藥物、考量其他比施用藥物更好的方法來治療疾病。如果使用藥物經評估是必要的，就要依病人個別情形、診斷、用藥之風險效益、有無使用其他療法，並考量劑量、用藥期間及藥品管理方式來選擇合適的藥物。有效而安全的使用藥品可以盡量減少藥物濫用、過量和劑量不足，還可以增加因多重用藥或用藥產生反效果之處理者的能力。

為執行這項政策，澳洲已有相關服務和干預措施，已開發包括NPS MedicineWise，居家藥物評估服務，藥品評估服務，Veterans'MATES，醫院的用藥安全措施等國家處方服務，以提高醫藥護專業人員對藥物之認知及提供消費者客觀資訊。

藉由此部分介紹，使職及與會者瞭解澳洲為提升藥物品質所做的

努力，澳洲之作為可作為我國未來執行多元化藥物資訊服務，及對醫藥護專業人員及民眾教服務育之參考。

三、 藥物安全監視目前面臨之挑戰

藥物安全監視（Pharmacovigilance）是衛生單位收集、監測、研究、分析與評估發生於病患使用藥物（包括藥品、醫療器材）時之不良反應。藉由藥物安全監視收集之數據，分析後可供衛生單位作出藥品後續管理如加註警語、限制使用對象、藥品下架等決策之依據，許多藥品如疫苗、新藥更是迫切需要藥物安全監視。藥物安全監視的通報來源來自藥廠、藥商、醫療院所及民眾，因藥物時常併用，導致醫、藥、護理人員無法釐清是藥物產生的不良作用、施用不當還是藥物本身的瑕疵所導致，不清楚何種情形需要通報，或知道要通報但不懂通報程序等，而導致通報比率低落，這種情形在中、低收入的國家更是明顯。這部分可以藉由蒐集藥物不良反應文獻資料、國與國間藥物不良反應資訊的交換，改善及簡化通報流程、擴大醫藥相關從業人員之教育、明確藥物安全監視相關管理法規而加以改善。

另外，在許多國家，藥物安全監視缺乏協調整合的系統，理論上完善的藥物安全監視系統應該含括不良事件的監測、通報和分析，產生有用的信息，使衛生機關得適時採用適當的干預措施，而構成一

個綿密的網絡系統，以確保公眾包括弱勢群體，如婦女和兒童的用藥安全。

藉由此部分介紹，得以瞭解藥物安全監視目前面臨之最大挑戰就是缺乏協調整合的系統，因此我國應該致力於建構更人性化更簡便的通報流程與介面，及透明公開之藥物安全訊息；另外，因通報尚需藥商及醫護人員的配合，需要其投注更多的人力、時間與經費，廠商及醫護人員是否願意配合，除了法令的配合外，更需要廠商的企業責任及醫護人員的理解，因此政府機關需花更多心力與廠商及醫護人員溝通，以藉由各方努力，使藥物安全監視體系更為完善。

四、 歐盟藥物安全監視相關法規最新修訂

歐盟原有藥物安全監視相關法規，包括歐盟法規（EU Regulations）、歐盟指令（EU Directives）、27 個成員國各國法律、藥物安全監視人用醫藥產品指引(Guidelines on Pharmacovigilance for Medicinal Products for Human Use) -9A 卷（2008 年 9 月）及 MHRA 的優良藥物安全監視實踐指引(Good Pharmacovigilance Practice ,GPV）（2009 年）。

歐盟擬藉由加強標準訂定、上市後監控研究和成立藥物安全風險評估委員會（PRAC）以強化上市後藥物監管及明確法律架構，故於 2010 年 12 月 31 日在其官方公報上發布修正歐盟藥物安全監

視相關法規，包括 2012 年 7 月生效的法規歐盟 1235/2010 及歐盟指令 2010/84/EU、6 月 19 日公布的實施條例（歐盟第 520/2012），及 2012 年 6 月 25 日發行，7 月 2 日生效的優良藥物安全監視實踐指引。

已修正公布之優良藥物安全監視實踐指引，包括：第一篇-藥物安全監視系統及其品質系統、第二篇-藥物安全監視系統主文件、第五篇-風險管理系統、第六篇-不良反應醫藥產品之管理和報告、七篇-定期安全性更新報告、第八篇－上市後安全性研究、第九篇-信號管理、附件一-定義；未公布正在準備中的部分，包括：第三篇-檢查(8 月 24 日協商結束)、第四篇-稽核(9 月 21 日協商結束)、第十篇- 附加監測（8 月 24 日協商結束）、第十五篇- 安全性溝通（9 月 21 日協商結束）；尚公布且未徵詢大眾意見的部分，包括：第十一篇-公民參與、第十二篇-持續藥物安全監測-持續的效益與風險評估，及持續與大眾溝通、第十三篇-事件管理、第十四篇-國際合作、第十六篇-風險最小化措施。

前述修正可使藥物安全監視相關人員之角色和職責明確化，同時藉由入口網站、公聽會使藥物安全監視達到更大的透明度，並可藉由建立藥物安全監視系統主文件及簡化報告來提高效率和使通報重複性降到最低。

歐盟各會員國為使藥物安全監視完善，應要維持和加強藥品不良反應通報，會員國、EMA 和歐洲的委員會並應與上市會管理者及大眾有良好的溝通，並藉由提供如：PRAC 會議議程、監測藥物名單、MAH 的主文件、PSUR 評估報告（結論）、RMPs 的摘要等資訊供大眾查閱，以提高藥物安全問題的透明度。

由此次2010年公布之歐盟藥物安全監視法規修訂內容可看出，歐盟目前在藥物安全監視上有三大重點，一為法律之明確性；二為藥物安全資訊之透明化；三為以提高通報率為目標，進行流程及文件之簡化。因此，我國可以參考歐盟修正法條之立意，先行檢視我國藥物安全監視相關法規之完整性，並參考其修正條文及持續關注歐盟相關法規之後續修正，藉以修訂我國藥物安全監視相關法規，以與世界接軌。

五、 台灣經驗分享

近來我國安眠藥使用量逐年升高，實地稽核亦發現佐沛眠(Zolpidem)安眠藥濫用情形增加，故本局利用本局管制藥品管理資訊系統與中央健康保險局全民健康保險資料庫數據比對分析，發現我國 Zolpidem 藥物使用量居所有安眠藥之冠，且自費開立情形有日益增高的趨勢，尤其是在診所部分，顯示有醫師會應病人要求而開立自費之 Zolpidem，以規避健保之查核，因 Zolpidem 使用後可能

導致成癮，或因夢遊副作用導致意外事件發生，亦可能遭流用於約會強暴用，為維護民眾健康及用藥安全，本局採取了加強宣導，加強稽核自費比率高的醫療院所，明確藥袋標示，及考慮提升Zolpidem之管制藥品列管等級等作為。為使各國瞭解我國為維護民眾用藥安全對防範安眠類藥物濫用所採取之管理作為，故職於該會議以「Management Strategies for Reducing Hypnotics Consumption in Taiwan」為題進行口頭報告。報告完後，該單元的主持人荷蘭Groningen大學Flora M Haaijer-Ruskamp教授，大為讚賞該報告是結合提升藥物安全概念，從發現問題，找出問題，到研擬解決策略，以解決問題的實務性報告，值得現場從事藥物安全監視的與會者參考學習，並期勉大家研究非僅是發現問題，更應針對問題採取實際作為，以預防問題再發生，來確保用藥安全及品質。

六、 國際交流

此次我國除由職口頭報告「Management Strategies for Reducing Hypnotics Consumption in Taiwan」外，還有成功大學高雅慧老師受邀至大會主題演講「Good Pharmacoepidemiology Practice in Asia, Why? And How?」，其學生賴嘉鎮發表二篇口頭報告「Risk of Extrapyramidal Syndrome in Patient with Schizophrenia Treated with Sulpiride」及「What is the Asian Pharmacoepidemiology Network (AsPEN)」與壁報論文「The

Trend of Adherence to Antiepileptic Drugs Therapy in Pediatrics Newly Diagnosed with Epilepsy in Taiwan」，藥害救濟基金會曾雅屏藥師發表壁報論文「Case Series of Peginterferon Alpha-2a-Associated Depression and Suicide Attempt Reported to Taiwan National Adverse Drug Reaction Reporting System」及「Metoclopramide-Associated Extrapyramidal Syndrome (EPS) in Patients under 18 years: Results from Taiwan National Adverse Drug Reaction Reporting System」兩篇。此次我國多人積極參與該會議，介紹發表我國的藥物不良反應通報相關研究、安眠藥管理模式、參加跨國性藥物流行病學研究之成果，讓世界各國認知台灣對藥物安全的努力。

職與 ISPE 主席（Dr. Stella Blackburn）、任教於與世衛組織合作藥物治療教學和培訓工作之荷蘭 Groningen 大學 Flora M Haaijer-Ruskamp 教授及哈佛大學公衛流行病學專家 Dr. K. Arnold Chan 交流、經驗分享與學習，Dr. K. Arnold Chan 並應邀於 101 年 11 月來台對本局人員進行藥物安全監視之演講。此外，成功大學高雅慧老師及其學生們於會中，更是努力宣傳並邀請與會者參加將於 2014 年 10 月 24-27 日在台灣舉辦的第 30 屆 ISPE 年會(Intrenational Conference on Pharmacoepidemiology & Therapeutic Risk Management, ICPE)，該次會議是首次移師於亞洲辦理之 ISPE 年會，又時值第 30

屆，意義重大。因此，我國參與這次會議，收穫滿滿，也做了很好的國民外交。

肆、建　議

一、密切注意歐盟最新藥物安全監視相關法規之進展，精進我國藥物安全監視機制

藥物安全監視為維護民眾用藥安全重要的一環，由 2010 年起歐盟陸續公布施行藥物安全監視相關修正法規，可以看出歐盟於藥物安全監視上的方向，因此我國應持續密切關注歐盟最新藥物安全監視相關法規之修正進展，檢視我國藥物安全監視相關法規，參考歐盟修正條文及其立法意旨，藉以修訂我國藥物安全監視相關法規，以精進我國藥物安全監視機制，與世界接軌。

二、借鏡澳洲藥物使用風險評估及管理，強化國內用藥品質及安全管理

藥物使用風險評估，需耗費人力、時間與經費，如何在安全、有效的用藥及用藥風險中取得平衡，是一困難的課題，因此，可以師法澳洲，藉由如居家藥物評估服務、藥品評估服務等相關服務和干預措施，型塑我國藥物安全評估的模式。另外，我國應檢討並改善不良反應通報的流程，使其更簡便，藥物安全資訊更公開，以強化我國用藥品質及安全管理。

三、瞭解各國藥物安全監視進展，建立合作與聯繫管道，汲取其經

驗，強化我國藥品安全監視暨風險管理機制

藥物安全監視為現在世界各國藥政管理之重點，除歐盟外，如美國、澳洲亦陸續有藥物安全監視法規的修正或新的推行措施，因此我國應持續關注各國藥政管理相關機關之網站更新資料，蒐集藥物不良反應文獻資料、並藉由參與國際會議，國與國間藥物不良反應資訊的交換，建立合作與聯繫管道，以汲取各國經驗，強化我國藥品安全監視暨風險管理機制。

附件一、議程

Program Details

Friday, 26th October 2012 – Pre-Conference Workshop

Introductory Pharmacoepidemiology

• 07:30 AM Registration • 08:00 AM Welcome coffee

Time	Topic	Speaker(s)
08:30AM	Introduction to pharmacoepidemiology and cohort studies	Soko Setoguchi (USA)
09:30AM	Identification of new user cohort in a case-cohort study in Japan	Kiyoshi Kubota (Japan) and Tsugumichi Sato (Japan)
09:50AM	Group discussion AND Questions & Answers	
10:50AM	Coffee Break	
11:10AM	Case-control studies	Soko Setoguchi (USA)
12:10PM	Lunch Break	
01:10PM	Operationalize definitions for cases, source population and controls in a case-control study on NSAIDs–Upper GI bleeding association in Japan	Kiyoshi Kubota (Japan) and Tsugumichi Sato (Japan)
01:30PM	Group discussion AND Questions & Answers	
02:30PM	Coffee break	
02:50PM	Interviewing cases and controls in a case-control study on NSAIDs – Upper GI Bleeding association in Japan	Kiyoshi Kubota (Japan) and Tsugumichi Sato (Japan)
03:10PM	Group discussion AND Questions & Answers	
04:10PM	Case only studies and implications of new user design in case-control and case only studies	Soko Setoguchi (USA)
04:40PM	Final comments and discussion by all	
05:10PM	Close	

Advanced topics in Pharmacoepidemiology

• 09:30 AM Registration •10:30 AM Welcome coffee

Time	Topic	Speaker(s)
11:00AM	Quality of drug use	Debra Rowett (Australia)
11:40AM	Pharmacovigilance in public health	Andy Stergachis (USA)
12:30PM	Lunch Break	
02:00PM	Benefit-risk assessment	K Arnold Chan (USA)
02:50PM	Registry for special population	Wei Zhou (China)
03:30PM	Coffee break	
03:45PM	Latest EU pharmacovigilance guidelines	John Talbot (UK)
04:45PM	Risk management	Stella Blackburn (UK)
05:15PM	Close	

Saturday, 27th October 2012 – Conference Program

• 07:30 AM: Registration • 08:00 AM: Welcome coffee • 08:30 AM: Opening formalities		
	Opening Keynote Address	Speaker
09:00 AM	"Safety and effectiveness through good pharmacoepidemiology practice" *Chairperson: Frank May (Australia)*	Brian Strom (USA)
10:00 AM	Coffee break	
Time	**Symposium/Session Title**	**Speaker**
10:30 AM	Symposium 1: 'Benefits and Risk Analysis - Concepts and Applications' *Chairpersons: Nilima Kshirsagar (India) and Arnold Chan (USA)*	
	Pharmacovigilance and risk management	Stella Blackburn (UK)
	Challenges in benefit risk assessment for regulatory decision and protecting patients	Nilima Kshirsagar (India)
	Benefit-risk assessment - Pharmaceutical industry's perspective	Wei Zhou (China)
	Symposium 2: 'Comparative Effectiveness Research' *Chairpersons: Chitra Lele (India) and Niteesh Choudhry (USA)*	
	An introduction to comparative effectiveness research and its links to the principles of good pharmacoepidemiology practice	Niteesh Choudhry (USA)
	Recent large comparative effectiveness studies for cardiovascular medications and devices: databases, linkage, and methodological considerations	Soko Setoguchi (USA)
	Use of a large simple trial design for comparative effectiveness research: The Ziprasidone Observational Study of Cardiac Outcomes (ZODIAC)	Brian Strom (USA)
12:00 PM	Lunch + Poster Session I	
	• Pharmacoepidemiology and Pharmacovigilance methods • Drug utilization studies • Post-marketing drug effectiveness and safety evaluation • Adherence	
	Contributed Paper Sessions	**Chairpersons**
02:00 PM	Contributed Paper Session 1: 'Risk monitoring and signal detection'	Nilima Kshirsagar (India) and John Talbot (UK)
	Contributed Paper Session 2: 'Towards a better quality of care'	Ganachari (India) and Chris Alderman (Australia)
03:30 PM	Coffee Break	
04:00 PM	Contributed Paper Session 3: 'Treat with caution! – Use and safety considerations of drugs in elderly and minors'	Gurumurthy Parthasarathi (India) and Frank May (Australia)
	Contributed Paper Session 4: 'Safety Considerations and Effectiveness of Commonly Used Medications'	Madhan Ramesh (India) and Brian Strom (USA)
05:30 PM	Close of sessions	

Sunday, 28th October 2012 – Conference Program

• 07:30 AM: Registration • 08:00 AM: Welcome coffee		
Time	**Contributed Paper Session**	**Chairpersons**
08:30AM	Contributed Paper Session 5: "Use and safety considerations of antibiotics"	Sujith Chandy (India) and Andy Stergachis (USA)
	AsPEN Symposium	
10:00 AM	Coffee break	
	Symposium/Session Title	**Speaker**
10:30 AM	Symposium 3: 'Best Practice in Drug Utilization Research' *Chairpersons: Sujith Chandy (India) and Debra Rowett (Australia)*	
	Antibiotics, what kind of research is needed for quality improvement?	Cecilia Stalsby-Lundborg (Sweden)
	Building evidence for a policy on rational antibiotic use through drug utilization studies	Sujith Chandy (India)
	Self-medication with antibiotics, and its determinants at national and individual level	Flora Haaijer-Ruskamp (The Netherlands)
	Symposium 4: Current Challenges in Pharmacovigilance' *Chairpersons: Dr. Y K Gupta (India) and Jude Nwokike (UK)*	
	Pharmacovigilance practices in pharmaceutical industry	K Arnold Chan (USA)
	Risk management plans in the EU	John Talbot (UK)
	Active surveillance for drug safety: Who, What, When, How?	Andy Stergachis (USA)
12:00 PM	Lunch + Poster Session II • Prevention and treatment of drug-induced diseases • Pharmacogenomics research and drug safety • Evidence-based medicine/pharmacy • 'Rational' drug use • Prevention of medication errors and drug misuse/abuse • Rare disease and orphan medicines • Pharmacoepidemiology and traditional medicines • Pharmaceutical policy and administration • Drug safety and risk management and Other related fields	
	Contributed Paper Sessions	**Chairpersons**
02:00 PM	Contributed Paper Session 6: 'Medication utilization, expenditure and management'	S Sriram (India) and Flora Haaijer-Ruskamp (The Netherlands)
	Contributed Paper Session 7: 'Potpourri'	Ponnushankar (India) and Kiyoshi Kubota (Japan)
03:30 PM	Coffee Break	
	Closing Keynote Address	Speaker
04:00 PM	'Good Pharmacoepidemiology Practice in Asia, Why? And How?' *Chairperson: B J Park (Korea)*	Yea-Huei Kao Yang (Taiwan)
05:00 PM	Concluding remarks, Awards and ACPE8 Announcement	
05:15 PM	Close	

- Name of the hall: Grand Ballroom 1
- Session 6: Medication Utilization, Expenditure and Management (2:00 pm to 3:30 pm)
- Chair: Flora Haaijer - Ruskamp and S. Sriram

Time	Title of the paper	Authors
02:00 pm	6 - A: Utilization Analysis of Antihypertensives in the Hospital of Shenyang Medical College from 2009 to 2011 (02 - 127)	Yang Ming Ping Jing Lu Yi1 Guan Xin Zhang Wenjie Li Jian Niraj Kumar singh Mayank Pandey Sandeep Kumar Dwivedi Pankaj Kumar Sadatia Rutviben Ravjibhai (China)
02:15 pm	6 - B: Safety of Medications in Community Pharmacy: knowledge and Attitude of Customers in Saudi Arabia (10 - 102)	Hisham Aljadhey Ghada Asaad Assiri Sinaa Al - Aqeel Abdulrahman Asiri Hazza Al - Ghamdi Mustafa Al - Jasser Mohammed Al - Yahya Hisham Ghomayjan (Saudi Arabia)
02:30 pm	6 - C: Management Strategies for Reducing Hypnotics Consumption in Taiwan (10 - 109)	Meng - Hsiu Wu Chia - Jung Chang Wen - Ing Tsay Ming - Neng Shiu Mei - Ling Hsiao (Taiwan)
02:45 pm	6 - D:Qualitative analysis of antidepressant prescribing for non - psychiatric inpatients in an australian hospital (12 - 103)	Alderman CP Kong L, Lau A (South Australia)
03:00 pm	6 - E: A retrospective study of drug prescribing pattern in Inflammatory bowel disease (IBD) in a tertiary care hospital (02 - 104)	Mukunda N. Tara V. Shanbhag Ganesh Bhat Smita Shenoy. (India)
03:15 pm	6 - F: Pattern of drug use in neonatal intensive care unit (02 - 105)	Dr. Jaydeep Bairagi Dr. Anjali R. Shinde Dr. C.C. Khanwelkar Dr. V.M. Thorat Dr. S.A. Jadhav. (India)

附件二、口頭報告「Management Strategies for Reducing Hypnotics Consumption in Taiwan」簡報資料

Management Strategies for Reducing hypnotics Consumption in Taiwan

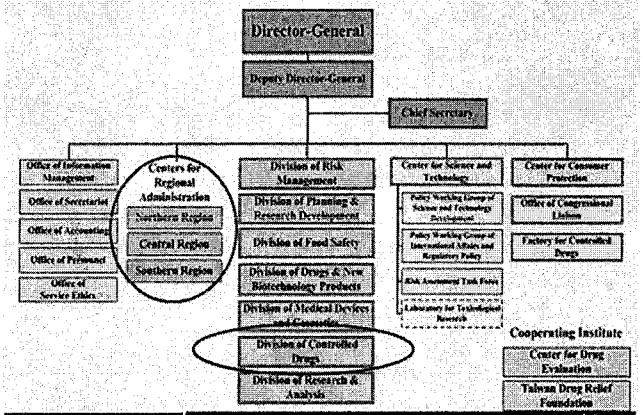
The 7th Asian Conference on Pharmacoepidemiology Bengaluru, India, 2012

Meng-Hsiu Wu, Chief,
Division of Controlled Drugs,
Food and Drug Administration,
Department of Health, Executive Yuan,
Taiwan, R.O.C.
28 Oct.,2012

Objectives

- The Taiwan's citizens prevalence of insomnia is **21.8%** in the 2009 survey.
- Hypnotics for the treatment of insomnia have revealed an increasing dependence by the public.
- Hypnotics are controlled drugs in Taiwan.
- Our study is aimed to investigate **the prescribing trends of hypnotics** and **develop the management strategies for reducing hypnotics consumption**.

TFDA Organization Chart



Methods

- **A retrospective study was implemented by comparing between two data sets:**

TFDA Controlled Drugs Management Information System Database	• abbreviated: CDMIS • the total consumption of hypnotics
National Health Insurance Database	• abbreviated: NHID • the consumption of hypnotics under National Health Insurance (NHI)

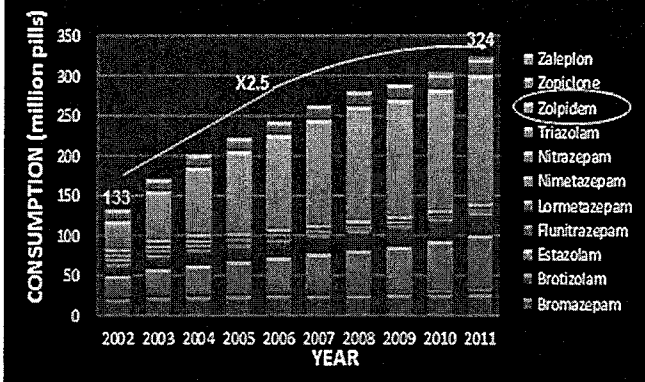
Results

- The consumption of hypnotics in Taiwan
- The usage pattern of Zolpidem in Taiwan
- The influence of using Zolpidem

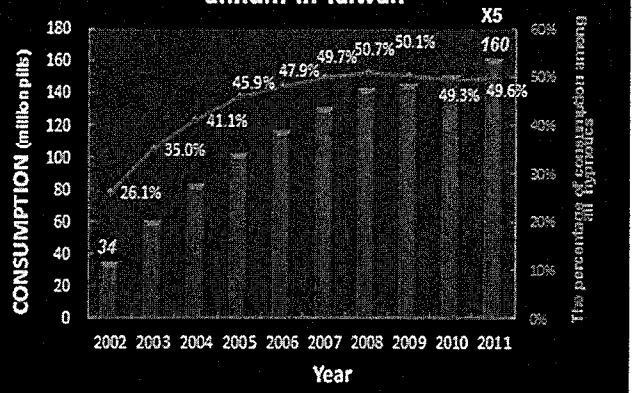
Result I
The consumption of hypnotics in Taiwan

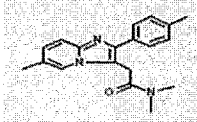
- **2002-2011 Total consumption of hypnotics per annum in Taiwan**
- **2002-2011 Total consumption of Zolpidem per annum in Taiwan**

2002-2011 Total consumption of hypnotics per annum in Taiwan



2002-2011 Total consumption of Zolpidem per annum in Taiwan





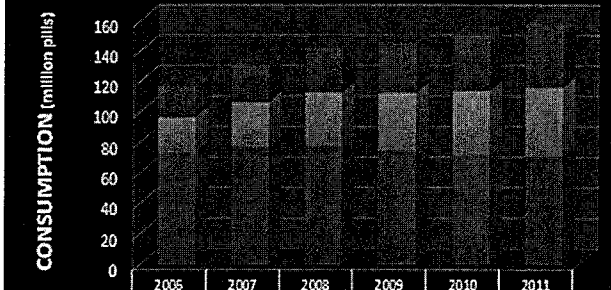
Zolpidem

- **Common names**：Stilnox® 、Ambien ®
- **Dosage**：10mg/tablets, 12.5mg/tablets
- **WHO ATC/DDD Index**：10mg/day
- **Mechanism**：mainly combine with the sub-receptor α1 in GABA receptor.
- **Indication**：insomnia
- **Side effect**：
  Drowsiness,Dizziness,Headache,Gross,Vomiting,Diarrhea,Unconsciousness, Sleepwalking, Addiction, Dependence, Tolerance, Withdrawal syndrome
- **Controlled drug:** schedules 4

Result II
The usage pattern of Zolpidem in Taiwan

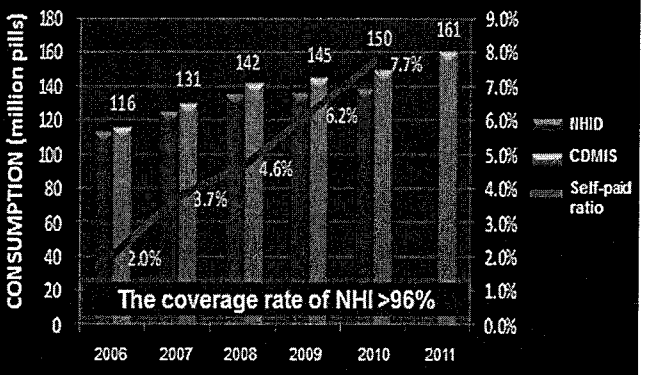
- **The consumption of Zolpidem per annum in pharmacies, clinics and hospitals (CDMIS)**
- **The Zolpidem use pattern at patients' own expense and covered by national health insurance**
- **The Zolpidem use pattern at patients' own expense in pharmacies, clinics and hospitals**
- **The prescription of Zolpidem under the National Health Insurance**
- **The cases of Controlled Drugs Malpractice proposed to the Review Committee of Controlled Drugs TFDA**

The consumption of Zolpidem per annum in pharmacies, clinics and hospitals (CDMIS)



	2006	2007	2008	2009	2010	2011
Pharmacies	19,951,317	24,330,151	29,419,301	32,965,046	36,720,102	42,154,965
Clinics	23,176,539	29,378,563	35,130,234	37,608,867	41,882,845	45,271,402
Hospitals	73,250,703	76,931,495	77,655,258	74,691,669	71,734,446	70,721,070

The Zolpidem use pattern at patients' own expense and covered by national health insurance



The Zolpidem use pattern at patients' own expense in pharmacies, clinics and hospitals

Year	Hospitals			Clinics			Pharmacies			Total Consumption (million pills)		Self-pay ratio
	Consumption (million pills)		Self-pay ratio	Consumption (million pills)		Self-pay ratio	Consumption (million pills)		Self-pay ratio			
	NHID	CDMS		NHID	CDMS		NHID	CDMS		NHID	CDMS	
2006	Some patients asked practitioners to fill self-pay prescription for avoiding records of National Health Insurance											.0%
2007												.7%
2008												.6%
2009	72.1	74.7	3.5%	34.6	37.6	8.0%	29.8	33.0	10.4%	136.3	145.3	6.2%
2010	69.0	71.7	3.8%	37.1	41.9	11.5%	32.7	34.7	11.0%	138.8	150.3	7.7%

2006~2010 The count of physicians who prescribed Zolpidem inappropriately under the NHI

YEAR	The count of physicians Who prescribed Zolpidem per patient per day ≧ 3 pills (A)		The count of physicians who ever prescribed Zolpidem (B)		Rate of physicians prescribed inappropriately (C=A/B)	
2006	3,165		23,007		13.76%	
2007	3,076		24,450		12.58%	
2008	2,899	-	25,844	+	11.22%	-
2009	2,471		27,329		9.04%	
2010	1,967		28,161		6.98%	

under the National Health Insurance regulations.

The Cases of Controlled Drugs Malpractice proposed to the TFDA Review Committee for Medical Use of Controlled Drugs

- ◆After inspection of Medical institutions prescribed controlled drugs, the authority will propose malpractice cases to the TFDA Review Committee for Medical Use of Controlled Drugs.
- ◆The inspector will collect all require evidences such as patient's medical record, medicine record, transaction record of the institution and the doctor's explanation if he found any malpractice of controlled drugs.
- ◆The comittee will review the malpractice cases.
- ◆The members of committee are doctors of psychiatric, pain management, gastroenterology, orthopedics and pharmacists, they will decide and discuss whether the prescription is proper issued or any possibility for the patient abusing drugs.

The Cases of Controlled Drugs Malpractice proposed to the TFDA Review Committee for Medical Use of Controlled Drugs

	2006	2007	2008	2009	2010	2011	Total amount
Proposed cases(a)							
Medical Malpractice Zolpidem Cases(b)							
The percentage of medical malpractice Zolpidem cases among total cases(b/a)							
Medical Malpractice Zolpidem Cases at Hospitals							
Medical Malpractice Zolpidem Cases at Clinics(c)							
The percentage of medical malpractice cases at clinics among total cases(c/b)	100%	66.7%	76.2%	100%	100%	90.9%	89.2%

- Clinics are the majority of those found improperly prescribing Zolpidem.
- This mostly involved physicians enabling patients to purchase the drugs at their own expense, leading to dosages that seriously exceeded the medical norm and therefore indicating that the improper medical prescription of Zolpidem has increasingly worsened.

Result III
The influence of using Zolpidem

- Drug abusers reported by psychatric institutions
- The Adverse Drug Reactions (ADRs) of Zolpidem
- The Zolpidem-related deaths cases from the Institute of forensic Medicine (IFM)

Drug abusers reported by psychiatric institutions

◆ Controlled drugs may lead users to addiction, and these abusers will ask for medical care from the psychiatric institutions, so TFDA require the professionals in the institutions report drug abuse cases to control the situation.

Drug abusers reported by psychiatric institutions

(person-times)

	2006	2007	2008	2009	2010	2011
Heroin	11,219	17,614	20,096	17,657	17,169	13,976
(Meth) Amphetamine	3,473	6,411	5,683	5,393	4,929	4,594
Cannabis	25	38	55	28	59	87
Benzodiazepines	872	576	442	421	345	428
Zopiclone	5	8	35	42	38	25
Zolpidem	**55**	**135**	**335**	**349**	**366**	**394**
Total	15,649	14,782	26,646	23,890	22,906	19,504

The Adverse Drug Reactions (ADRs) of Zolpidem

Drug / Type	1 Zaleplon		2 Zolpidem		3 Zopiclone		4 Flunitrazepam		5 Triazolam	
	case	%	case	%	case	%	case	%	case	%
Complication of drug injury or overdose	0	0%	1	2%	1	3%	1	9%	0	0%
Nervous disorder	0	0%	56	41%	20	59%	29	43%	7	58%
Psychological disorder	2	40%	23	18%	5	24%	5	13%	2	17%
Respiratory disorder	1	20%	2	0%	0	2%	1	2%	0	0%
Heart disease	0	0%	4	3%	0	0%	1	2%	1	8%
Eye disease	0	0%	3	2%	1	3%	0	0%	0	0%
Gastrointestinal disorder	0	0%	12	9%	2	6%	1	2%	0	0%
Liver disorder	0	0%	2	0%	0	0%	1	2%	0	0%
Nutritional and Metabolic disorder	0	0%	2	0%	0	0%	0	0%	1	8%
Musculoskeletal disorder	0	0%	0	2%	0	0%	0	0%	0	0%
Disorder of skin and subcutaneous tissue	2	40%	7	2%	1	3%	0	0%	0	0%
Other disorders	0	0%	20	8%	1	3%	4	8%	0	0%
Pregnancy and delivery	0	0%	0	0%	0	0%	1	2%	0	0%
Urinary system disorder	0	0%	0	0%	0	0%	1	2%	0	0%
Blood Vessel Disorders	0	0%	0	0%	0	0%	2	5%	1	8%
Other survey	0	0%	2	0%	0	0%	1	2%	0	0%
Total	5	100%	10	100%	34	100%	44	100%	12	100%

The Zolpidem-related deaths cases from the Institute of Forensic Medicine (IFM) unnatural death

YEAR	2002	2003	2004	2005	2006	2007	2008	2009	2010	Total
Total cases from IFM (A)	1,446	1,459	1,579	1,841	1,816	1,661	1,866	1,796	1,980	16,818
Drugs-related deaths cases (B)	152									
Rate of Drug-related deaths cases (B)/(A)	10.5%									
Zolpidem-related deaths case (C)	7	10	10	16	26	30			39	218
Rate of Zolpidem-related deaths cases (C)/(A)	0.48%	0.69%	0.63%	0.87%	1.43%	1.81%	2.30%	2.00%	1.97%	1.30%
Rate of Zolpidem-related deaths cases in Drug-related deaths cases (C)/(B)	4.6%	6.6%	6.6%	10.5%	17.1%	19.7%	27.1%	14.8%	13.2%	10.1%

The Bureau of the National Health Insurance set new regulations of prescribing Z-Drugs in 2009

Social harm of Zolpidem(News)

2007.10.2	For relieving addiction, a nurse stole her colleague's NI card. Taipei- a nurse stole her colleague's NI card for getting Stilnox. Her family took her NI card away to stop her abusing sleeping pills.
2008.3.18	A hooker was sentenced for 42 months due to knock the guest out and stripped him bare. Taoyuan-a hooker drugged a guest by putting a sleeping pill in her mouth, she passed the pill to the guest's mouth when they kissed. Then she took everything away from the guest. The victim authorized for 3 days and sought the hooker to the police.
2010.7.22	Mistakes in improving memory, a student bought 600 tabs. from the Internet. Taipei- a senior high girl bought more than 600 sleeping pills for improving memory - it caused her delirious and committed suicide several times until being sent to the hospital. -
2010.11.04	Female guest stayed in a hostel bring sexual harassed. Hualien-The owner of "Little Leo's hostel", drugged a female guest in food and pursued on her.
2011.1.4	Woman couldn't sleep without taking 90 sleeping pills. A 36-years-old lady abused Stilnox, she couldn't sleep without taking them - she has consulted the doctor for 376 times.
2011.4.5	Artist call on the public to have sleeping walks by eating drugs. An artist call on a "Hundreds sleeping walking", asked volunteers to take sleeping pills and join his exhibition.
2011.8.2	A clinic convicted of drug fraud Taipei-Kang-ning clinic was found that forgery of prescription for selling controlled drugs since 1994.
2011.11.10	Over 1,000 pills a week The medicine found that the situation of abusing Stilnox is very serious, it caused 3 dead - someone even took over 1,000 pills in a week.
2011.12.5	A lady bought sleeping pills massively and could not recognize her parents. Taichung- a lady bought Stilnox from pharmacies, she took a dozen of Stilnox for 2 months - totally over 5,000 tablets.

Discussion

- According to the results of data analysis, we develop some appreciate intervention strategies to reduce hypnotics consumption through a collegiate discussion by professionals and officials.
- We must take management strategies for reducing hypnotics consumption in Taiwan.

Improve the supervision measures from Taiwan FDA

- Enhancing inspect the medical institutions which use large quantities of Zolpidem or filled many self-pay prescriptions.
- Make public education campaigns to educate the public and physicians about the harm and use hypnotics properly.
- To counteract Zolpidem abuse in Taiwan, TFDA has undertaken deliberations to elevate Zolpidem from a Schedule 4 to a Schedule 3 controlled drug.

Acknowledgement

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