出國報告（出國類別：其他）

參加「第三屆世界製藥學術大會」出國報告

（Third Pharmaceutical Sciences World Congress, PSWC 2007）

服務機關：行政院衛生署中醫藥委員會

姓名職稱：張麗晴專員

派赴國家：荷蘭

出國期間：民國 96 年 4 月 20 日至 4 月 27 日

報告日期：96 年 7 月 19 日

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姓名職稱：張麗晴專員

派赴國家：美國

出國期間：民國 96 年 4 月 20 日至 4 月 27 日

報告日期：96 年 7 月 19 日

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公務出國報告提要

頁數　：25 含附件：□是☑否

出國報告名稱：

參加「第三屆世界製藥學術大會」出國報告

出國計畫主辦機關／聯絡人／電話

中醫藥委員會　鍾慧茹　02-25872828 ext.267

出國人員姓名／服務機關／單位／職稱／電話

張麗晴 衛生署中醫藥委員會 研究發展組 專員 02-25956830

出國類別：□1 考察□2 進修□3 研究□4 實習☑5 其他

出國期間：民國 96 年 4 月 20 日至 4 月 27 日

出國地區：荷蘭

報告日期：民國 96 年 7 月 19 日

分類號／目：J1／中醫　J0／綜合

關鍵詞：中醫藥、PSWC、藥品安全監測

內容摘要：

製藥科學世界會議 (Pharmaceutical Sciences World Congress, PSWC)，係由國際藥學聯盟(International Pharmaceutical Federation, FIP)主辦，歐洲藥學會（European Federation for Pharmaceutical Sciences, EUFEPS） 協辦。本次會議於 2007 年 4 月 22 至 25 日假荷蘭阿姆斯特丹 RAI 國際會議中心舉行，大會主題爲：「世界衛生之重責—合適的藥物治療」。會議架構涵蓋 6 場大會演講、36 場不同主題之同步研討會、10 場圓桌討論、11 場歐洲藥學會午後討論及 1000 篇壁報展示，超過 3000 位來自世界各國的科學家、研究人員及學術界人士參加。

行政院衛生署中醫藥委員會爲全國最高中醫醫政、中藥藥政最高主管機關，特派員參與此研討會，以掌握國際醫藥近期研究相關發展之現況，另本會爲落實行政院衛生署「國際業務協調會議」決議事項，並鑑於本會 2006 年開辦新興科技業務「中醫藥健康安全防護網計畫」宜提供國際學術界參考，爰撰寫是項計畫執行摘要，以「The safety control program of herbal medicine in Taiwan」爲題投稿，並業經本次大會科學委員會審查接受，符合本會 2007 年中醫藥研究成果擴散年之目標。本次大會議程與本會推動科技業務主軸相關，參與人員皆爲國內及國際醫藥界專業人士，參加本次大會將有助於瞭解及掌握國際醫藥衛生政策趨勢及學術發展現況。

目　　次

摘要

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關鍵詞：中醫藥、PSWC、藥品安全監測

壹、 目的

行政院衛生署中醫藥委員會為全國最高中醫醫政、中藥藥政最高主管機關，此次特派員參與此研討會，以掌握國際醫藥近期研究相關發展之現況，另本會為落實行政院衛生署「國際業務協調會議」決議事項，並鑑於本會 2006 年開辦新興科技業務「中醫藥健康安全防護網計畫」宜提供國際學術界參考，爰以「The safety control program of herbal medicine in Taiwan」為題投稿，並經 PSWC 大會科學委員會審查接受，符合本會 2007 年中醫藥研究成果擴散年之目標。本次大會議程與本會推動科技業務主軸相關，藉由收集相關資訊與經驗，將作為未來推動台灣中醫藥科技發展及藥品安全之依據與參考，以促進我國中醫藥之現代化及國際化。瞭解及掌握國際醫藥衛生政策趨勢及學術發展現況，有利於本會未來政策制訂參考，促進國際接軌。

貳、 會議過程

一、 行程及工作記要

4 月 20-21 日	啓程（台北→荷蘭阿姆斯特丹）
4 月 22 日	報到
4 月 23 日	出席 PSWC 會議
4 月 24 日	出席 PSWC 會議
4 月 25 日	出席 PSWC 會議
4 月 26-27 日	返程

二、會議進行方式

製藥科學世界會議 (Pharmaceutical Sciences World Congress, PSWC)，係由國際藥學聯盟(International Pharmaceutical Federation, FIP)主辦，歐洲藥學會（European Federation for Pharmaceutical Sciences, EUFEPS） 協辦。此次 PSWC 年會議題分別討論未來治療方向發展及藥學研究科技二大方向，研討主題包括個人化醫療、特殊療法、藥物傳遞系統、標靶設計及醫藥化學、藥動學及藥效學、製藥技術、藥物分析及品質確效、藥物基因學、系統生物學技術、臨床藥學及藥物流行病學、上市前後評估監測等重要醫藥學術主題之最新研發進展（附錄一）。本次會議於 2007 年 4 月 22 至 25 日假荷蘭阿姆斯特丹 RAI 國際會議中心舉行，大會主題爲:「世界衛生之重責—合適的藥物治療」。邀請世界醫療及製藥科學界的頂尖人士，諸如 EMEA（歐洲醫藥評審組織）主席 Dr. Thomas Lundgren 及 WHO 官員 Richard Laing 蒞臨演講，會議架構涵蓋 6 場大會演講、36 場不同主題之同步研討會、10 場圓桌討論、11 場歐洲藥學會午後討論及 1000 篇壁報展示，超過 3000 位來自世界各國的科學家、研究人員及學術界人士參加。

三、會議內容重點

大會開幕首先由荷蘭文教科技部長 Dr. Ronald Plasterk 致詞，Dr. Ronald Plasterk 本身是位卓越的分子發育學家，基於高齡人口的拓展，提出這個世界絕對需要新藥之議題，提醒藥學研究界在目前及未

來必須重視的責任及挑戰。他指出醫藥專業人員更應接受不同創新方式的教育，以面對未來健康照護的需求。他的演講內容也點到轉譯醫學（Translational Medicines）的重要性，轉譯醫學是一項可填補連結基礎醫學及病患需求間距的學門，有助於銜接學術發展新知、應用研究成果及全球性健康議題間的差異。

大會邀請 Organon 全球研發部高級副總裁 Dr. David Nicholson，也以製藥產業界的觀點回應 Dr. Ronald Plasterk 的說法，認爲轉譯醫學可解決新藥開發的需求並促使新藥物加速完成上市，跨越現今許多醫藥品於第二期臨床試驗失敗的藩籬。Dr. David Nicholson 並強調美國新醫藥品近 20 年來著眼全球層次，核准率提升外，亦積極開發候選新藥，此部分歐洲已逐漸落於美國之後。

此外，EMEA 主席 Dr. Thomas Lönngren，同樣也強調法規、研究及產業界應遵循共同路徑並一起努力，尋求具新潛力的藥物直至面世，如此才能有效符合日益擴大的老化人口群之健康醫療需求。

由於本會重大業務包含中藥藥政管理、中藥研究開發、中藥臨床試驗、中藥不良反應及安全性防護等主政範疇，故本次參加之議題以藥物安全性、草藥交互作用、藥物流行病學、藥物基因體學等學術發展之研發現況爲主。報告人茲就相關領域演講內容節錄說明如下：

（一）大會演講：

本次大會共安排了六場非同步之大會演講，其演講內容均設定於全球性醫療需求主題之下，內容簡述如後：

1. **What are the main challenges for world health?**

WHO高級官員Dr Richard Laing,曾擔任美國波士頓大學教授及臨床醫師，是WHO藥物監測及藥價研究專家，亦是近來WHO在歐洲及全球推動" Priority Medicines"推手之一，他的演講呼籲重視全球因疾病產生的負擔，以及醫療系統貧乏產生的差距。並進一步討論歐洲大陸及全球應將一些迫切的醫療問題列爲優先研究議題，例如微生物抗藥性、流行性感冒大流行、輕視的疾病及兒童醫學。另外也提及製藥領域中，主要影響創新的障礙，包括藥價、支付標準及法規限制等。另舉例荷蘭傑出的藥學機構，同時考量公眾及個人利益來支持藥學創新，並建議藥物學術界應將自己的研究工作更合乎世界醫療的需求，產業界及學術研究機構能在未來發展計畫中優先加入全球公共衛生觀點。

2. Transforming 'art' into 'science' in dosage form design - achievements and challenges

英國Bradford大學教授Peter York是製藥材料工程專家,研究主題著重於在製藥系統中的藥物分子傳遞、晶體工程、人工智慧的應用等。這個演講著重於近期有關劑型設計的關鍵性進展，尤其著重以電

腦化生物學概念的工程基礎，應用於在藥物處方的設計概念上。近期及未來在衛生照護上更需要安全性、品質佳及有效性的醫藥支持，因此在劑型設計上以科學性原則應用，將有利於藥物的傳遞系統。

直到近年，將藥物成分轉變形成處方藥的過程，一般來說適合大藥廠大量製造成具效果的產品，但至少一部分應考量以藝術爲基礎，而非侷限於科學性原則。然而，隨著在劑型效能的標準及精準的需求逐漸增加， 就藥物（大）分子而言，化學、傳遞路徑、藥動學及藥效學等這些有關劑型設計及製藥的科學，已有長足的進步應付並解決挑戰，這也提供了一種科學性探索知識的平台。而「分子製藥學」的概念始於 1960 年代末期，爲健康及製藥科學上，提供另一種平行方式且具遠見基礎的分支研究主軸。像利用化學、物理、結構生物及物理學的各式探針，研究藥物成分及其他組成物質，也成戲劇性改善高解析分析儀器，並可利用屬於價廉的電腦成本，去重組複雜且多重組成分的藥物傳遞系統，毫無疑問地，對於劑型設計上，所產生各式科學性嚴謹及機械化的過程提供協助。隨著過去 30 年的演進過程，例如口服、非口服及經皮吸收等改良的產品，包括藥品植入物，到最近成功經由呼吸道途徑傳到全身的快速藥品吸收系統，另外的產品包含暫時啓動的磁粒、鎖定目標的藥物傳遞系統，這些以科學基礎，增加創新性的方式，令人印象深刻。而重大的挑戰仍持續存在，像是不易溶解藥物的有效性及其傳遞路徑與標靶的生物科技產品。其他主題關注有效率進行醫藥品的設計同時在一般人口及特殊群體有著不同的

藥物基因圖譜，並提供合適的法規規範及藥物組成的品質。在這些方面，具有預測及最適性藥物傳遞系統的能力，是否具快速有效率的設計及製造能力將是關鍵。

3. A**re we meeting the challenges of resistance to anti-infective drugs and of newly emerging infectious diseases?**

Larry Schlesinger 教授是美國俄亥俄州大學微免感染中心主任，也是感染性疾病、微生物病原及生物防疫之研究教育專家。他認爲隨著新病原連續產生突來的威脅，以及固有病原體產生抗藥性，民眾對傳染病警覺性倍增，一些病原體具有高致病性、高死亡率及快速全球蔓延的潛力，導致社會付出龐大的經濟代價，此外像是愛滋病、結核病、瘧疾及登革熱持續在某些國家歷久不衰 目前已是地球村的國際社會更容易受影響 導致全世界每年超過四分之一的人口死於感染性疾病。隨著這些全球性感染疾病挑戰增加，如何預防治療的嶄新因應方式更形迫切。新的診治策略需要對人體生理學、微生物學及生態環境間的交互作用具有更完備的認識。基因體學及藥物基因體學提供機會，特別針對在藥物開發過程，可同時考量到新藥標靶的發展，以及特定病患族群對特定藥物潛在的正向反應。在這個領域中，許多跨學門的團隊合作正逐漸增加，有效地運用這些技術。然而也需要製藥產業界產生興趣並提供有意義的投資，最終若想有效殲滅全球主要的感

染性疾病，唯有透過產業界、學術界、非政府及國際組織強力穩固的合作。

4. Will novel approaches to the treatment of cardiovascular disease prove highly effective?

荷蘭阿姆斯特丹大學血管醫學研究中心主任John J.P. Kastelein教授，曾發表超過 4000 篇優秀論文被刊載於*Lancet*、*New England Journal of Medicine, JAMA and Circulation* 等著名國際醫學期刊，他也是荷蘭動脈硬化學會主席。Kastelein教授表示隨著藥物能有效控制lipoprotein的代謝、血壓及血糖濃度，由心血管疾病所導致的疾病及死亡的發生率已經逐漸下降，然而多數心血管疾病的發生仍是難以預防。幸而有以下三項重要的發展，即將在不遠的未來，轉變爲一般性臨床治療，或許能協助我們對抗這些不利的疾病統計數據。這些發展包括cannibinoid receptor antagonists，是一種能提升HDL的藥物，同時也促使合成apolipoprotein (apo) B mRNA的 inhibitors，而apolipoprotein (apo) B mRNA促成大部分atherogenic protein留在循環中。另外endocannabinoid system，此爲一種neuromodulatory 系統，在許多生理功能中扮演重要角色，包括食物攝取及能量恆定的運作。藥理學上CB1 receptors的阻斷是一種治療多重心臟代謝性危險因子的新科技。CB1 blocker，rimonabant的臨床試驗數據顯示，能明顯降低具肥胖及心血管疾病病患之體重與腰圍，也能有效同時改善lipid

profile及glycemic control。而HDL-C濃度，此與心血管疾病盛行率間存在密切關係，特別能造成脂質斷裂的藥物成分，將可發揮額外的臨床效益。鑑於cholesteryl ester transfer protein (CETP) 的抑制已有長足的進展，相關成分已證實能分別增加HDL-C到 34%或 106%。有一種高血脂症的特別療法即利用antisense apolipoprotein B，ApoB是所有atherogenic particles（VLDL、IDL及LDL）最主要的結構蛋白。雖然最近藉由小分子療法直接抑制apolipoprotein尚無法完全成功，但利用Antisense科技應用於阻斷apoB mRNA translation的機轉，將可能直接抑制apolipoprotein B的形成。

5. Drug resistance in cancer chemotherapy

在日本東京大學任職超過 30 年的東大榮譽教授Tsuruo博士，是抗癌藥物抗藥性研究專家，1981 年他發現verapamil爲多重抗藥性解決因子，近年則專注於細胞凋亡機制與癌症細胞抗藥性相關性之研究。Tsuruo教授介紹他最近的研究成果。由於近來已有許多獨特的抗癌藥物被發展應用於癌症分子治療，Tsuruo教授在癌症分子治療研究上，主要著重於癌症治療主要的問題－抗藥性。P-glycoprotein (P-gp)是多重抗藥性主要的關鍵，Tsuruo教授找出P-glycoprotein (P-gp)的抑制物－MS-209，目前正進行臨床研究中，雖然P-gp是典型且普遍皆知的抗藥性媒介物質，但癌細胞仍有其他的抗藥機轉。在這樣的認知下，Tsuruo教授進一步探索細胞凋亡（apoptosis），細胞凋亡抑制因子及

細胞凋亡拮抗機轉發現：p53 及apoptosome (mitochondria) signaling，Akt survival-signaling，telomerase及 tankyrase 路徑。Apoptosis 是一種調控藥物敏感性的途徑，而apoptosis拮抗機轉則是直接與抗藥性相關，Tsuruo教授已確認glyoxylase 1 是一種apoptosis拮抗性蛋白質，在實體腫瘤（solid tumors）中發揮抗藥性。實體腫瘤有另一種抗藥性的機轉；稱爲UPR (unfolded protein response)，在呈現UPR的狀況下，Tsuruo教授確認一些因素具有選擇性的細胞毒性；P53 的突變及apoptosome的缺陷也導致抗藥性。同時也發現在癌細胞中繞過這些缺陷，選擇性引發apoptosis的因素；Apoptosis抑制蛋白及PI3K-Akt 存活訊息傳遞路徑與腫瘤發育息息相關，也影響了抗癌藥的抗藥性。在這部分，Tsuruo教授分離出IAP及apollon，並研究蛋白質cytoprotection的功能，發現一些成分能影響PI3K-Akt的存活路徑。還有telomere的自控機制可刺激引發apoptosis，而大部分的腫瘤利用telomerase藉此規避。Tsuruo教授發展出一些telomerase的抑制因素，以及利用telomere導向的複合型治療模式。

6. **Recent progress in prion biology**

瑞士蘇黎世大學神經病理研究所研究員Mathias Heikenwalder是prion研究專家，經他介紹Transmissible spongiform encephalopathies (TSE)是人類及動物一種致命的神經性病變疾病。致病因子prion的蓄積，不僅發生在中央神經系統也存在於次淋巴器官。此演講除介紹在免疫系統中，周邊prion病變的形成外，並著重在extraneural及

extralymphatic prion感染的發展機制。尤其是相同的pro-inflammatory cytokines及homeostatic chemokines均參與淋巴新生，歸類阻隔各免疫細胞，呈現決定性的分子轉移反應，形成extraneural prion 的蓄積。

（二）研討主題：

本次 PSWC 大會共安排 36 場不同主題研討會，共計約 180 項演講議題。每場研討會主題均包括有 3 位受邀請之演講者，以及 2 位由大會評審挑選出之傑出口頭論文之演講者。由於研討會採同步平行方式進行，報告人茲就業務相關領域演講內容節錄說明如下：

1. 藥物流行病學及藥物利用型態研究

有關跨國性觀察使用高血壓治療藥物持續性之研究文獻較少，荷蘭 Utrecht 大學 Van Wijk 教授講述一項老年人口使用持續性高血壓治療藥物的跨國性研究。此研究主要是描述並比較在美國賓州、加拿大 B.C.省及荷蘭境內老年人口，有關持續性高血壓治療藥物的使用型態。屬回溯型 cohort 研究，樣本來源分別是美國賓州 Medicare 保險人、加拿大 BC 省公民及荷蘭 PHARMO-database 內之公民。每一族群包括 65 歲以上，進行控制血壓治療的民眾，且從 1998 年 1 月至 2003 年 12 月，並持續追蹤至少 365 天者。主要的評估觀察基準是至少連續 180 天未服藥的比率，結果在一開始治療的第一年曾經連續 180 天未服藥的比率，在美國 9,664 位 Medicare 承保人佔 23.3%，25,377 位加

拿大人佔 23.4%，24,603 位荷蘭人佔 24%。六年追蹤後，比率分別增加至 41.1%、36.3%及 38.2%。尤其以年紀較老的男性居多，且與第一年是否即出現服藥間斷的情形有關。另外若曾經有急性心肌梗塞及高血脂病史的民眾，較能持續服藥。儘管在這三個國家的健康照顧系統，藥物給付方式不同，未持續服藥的型態仍是相當類似，也說明此間斷服藥習慣並不會因國籍、衛生醫療系統、處方藥給付制度等因素而顯現不同趨勢。

2. 草藥交互作用

澳洲雪梨大學 McLachlan 教授指出一般民眾經常存在同時服用處方藥及草藥的習慣，亦缺乏對潛在不良反應風險相關的資訊。有關草藥與處方藥交互作用，有關的藥動及藥效學機轉完整的知識，也必須有系統性的建立。讓醫療人員及病患雙方，能評估這些交互作用之臨床意義，做正確有效的處置，避免不良後果的風險。評估有關草藥及處方藥交互作用已發表的實證文獻，必須仔細檢視其臨床試驗的設計，試驗用之草藥產品品質及其劑量使用。而大多數具嚴謹實證數據結果均來自 *in vivo* 研究，反之，由 *in vitro* 產出的研究數據較具爭議，因爲許多草藥的組成分及代謝方式並不等同於 *in vivo* 在血液中的濃度表現。草藥的研究，諸如 *Ginkgo biloba* 及 *St John's wort* 已經顯現 *in vivo* 及 *in vitro* 研究數據間之差異。有關草藥及處方藥交互作用的臨床反應，取決於藥物間交互作用的特性、藥物安全閥值、劑量及治療時間與病人的實際臨床狀態。當合併使用草藥及處方藥時，在經常

服用多重藥物的老年病患，正處於不良藥物反應高風險之下，若要評估病患是否具嚴重草藥服用風險，必須詳加檢視病患自己所服用的各類醫藥品及其劑量，另一方面也需系統化的正確資訊，以作爲臨床決策參考。幫助消費者無論是純粹使用草藥，抑或是合併服用處方藥，均能擁有潛在的效益，避免傷害。這也是醫療人員應扮演的關鍵角色。

3. 藥物安全資訊

瑞典大學斯德哥爾摩大學研究員 Eiermann 介紹藥物交互作用資訊庫－Sfix，由於藥物交互作用 Drug drug interactions (DDI:s)是藥物治療中普遍相當重要的問題，DDI:s 會造成不良反應或藥效減損，但 DDI:s 是可以避免的，一般醫師經常未察覺病人服用的各項藥品間，所產生之交互作用，而 Computerised decision support systems (CDSS:s)包含 DDI:s 的資訊能協助提高醫師改善藥品處方籤的品質。藥物交互作用資訊庫 Sfix 是瑞典及芬蘭的一項隨時更新的共同計畫，以便應用於臨床。這個資料庫以 Extensible Markup Language (XML)語言架構，文獻搜尋的 standard operation procedure (SOP)分爲 8 種類別並有專屬的相關搜索字元及策略；交互作用的警示文字由 4 種資訊組成（consequence, recommendation, mechanism, background），尤其著重於可應用的建議事項。而參考文獻也嵌入每一個字元，字元主要是英文模式，相關專業資訊由臨床藥師及醫師相繼翻譯爲其他語言，包括藥物組成分亦在其中。初期將在 5 所健康醫療照護中心試辦在 4,897 個病患診次中，出現 604 次交互作用的警訊，病患發生率平均 16.7%，

其中 53 次警示經由醫師判讀。超過 65%使用者認爲 Sfinx 在每天開立處方之實際應用上助益甚大。

4. 藥物副作用機轉研究

奧地利維也納大學研究員 Germann 博士介紹有關 COX 抑制劑對血腦屏障（BBB）的影響研究，由於愈來愈多研究顯示長期使用 COX 抑制劑會影響心血管功能的副作用，而血腦屏障維持腦部微循環，對於神經元活性及功能影響甚鉅，tight junction 蛋白則是進一步控制血腦屏障的整合度。因此本研究以 COX 抑制劑影響血腦屏障之內皮細胞爲假說，以 BBB 仿生細胞株（PBMEC/C1-2 及 ECV304）及初代 HUVEC 細胞進行實驗，在初步實驗中，這二種細胞株及 HUVEC 經由 ELISA 確定，存有 tight junction protein Occludin, Claudin-5 及 ZO-1，黏合分子 ICAM-1 及 VCAM-1，以及內皮細胞標幟 von Willebrand Factor (vWF)，並進一步分析 TNFα 及 γIFN 的影響，隨後加入 Indomethacin (COX-1 inhibitor)、Lornoxicam (COX-1 與 COX-2 抑制劑)及 Celecoxib (COX-2 inhibitor)，觀察對上述細胞分子之影響。初步成果顯示，TNFα 能刺激 ECV304 及 HUVEC 細胞株內黏合分子 ICAM-1 的表現，γIFN 對上述細胞分子則無任何影響。然而，COX 抑制劑對 PBMEC/C1-2 及 HUVEC 細胞造成影響，但對 ECV304 細胞無任何反應。其中 Celecoxib 具有高度損害內皮細胞的潛在能力，比起 Indomethacin 與 Lornoxicam，更易傷害 tight junction protein Occludin，ZO-1 及黏合分子 ICAM-1。此研究進一步支持 COX 抑制劑

造成心血管功能副作用之觀點，COX 抑制劑不僅影響生理機轉亦造成內皮細胞損傷。

5. 建構系統藥理學研究

新加坡大學基因體研究中心執行長劉德斌教授表示，系統生物學係在一個細胞或有機體中，經由所有細胞生化分子網絡，探索生物功能的一項學門，目前正積極利用系統生物學科技，建立預測藥理學的架構。這個系統是利用在 *in vitro* 及人類腫瘤中的 p53 transcriptional response。首先分析 251 位乳癌初期病人之 p53 基因序列及 32-gene 表現，其次分析調控 p53 功能之 glycogen synthesis kinase-3beta (GSK-3beta)。GSK-3beta 主導損害 p53-dependent transactivation 的目標，包括 p21 and Puma，但卻促進 Bax 的 p53-dependent conformational activation，導致引發 apoptosis。因此，暴露在化學治療劑下，p53-mediated damage response 形成後，cell cycle 停止，轉變進入 apoptosis。這個藥物成分療效取決於初期腫瘤 p53 狀態可否評估的基礎上。根據這些觀察認爲進一步精確測定 p53 的機轉更形重要，因此發展出 couples chromatin immunoprecipitation (ChIP) 及 paired-end ditag (PET) 定序技術。根據這些成果，更精確描繪出 p53 binding motif，以及至少 542 個 binding loci，探索 98 個以前未確定的 p53 target genes 及其功能，諸如 cell adhesion 與 motility。最後並證實 p53-dependent 腫瘤生成機轉與初期癌症病患間之臨床相關性，這些成果已被國際一流學術期刊 *Cell* 接受刊載。.

6. 新藥上市前之 outcome measurement

我國陽明大學黃文鴻教授經大會邀請，講述有關藥品上市前相關安全性評量策略，2004年9月Merck's Vioxx® refecoxib因長期使用（>18 months）易引發高的thromboembolic cardiovascular events而下市。2006年12月FDA暫停Pfizer公司一項大型心血管療法第3期臨床試驗，因爲接受torceptrapib/atorvastatin(T/A)組合療法的患者，與僅接受atorvastatin的患者相對死亡率上升。這兩項事件不僅使藥廠股價下降，造成200-300億美元損失，也引發大眾對使用新藥病患權益之關切，各國衛生單位也開始重視該類藥品（COX-2 inhibitors）的安全性，進行各種資料分析研究及藥物流行學之研究。另NSAIDs類藥品之安全性也進行相關之再評估。黃教授利用我國健保資料庫分析2001-2003年，長期使用rofecoxib、celeocxib與meloxicam的病患，觀察9,602位病患發生AMI、angina、stroke及transient ischaemic attack (TIA)之風險，結果發現使用celecoxib的病人較使用meloxicam的病人發生心血管問題的風險爲低，相較於使用meloxicam的病人，使用rofecoxib的病患並不具較高的心血管疾病發生風險。上述研究成果亦於2006年被著名國際期刊*Drug safety*接受刊載（附錄二）。黃教授並進一步指出，要改善新藥發展的安全性，應從諸多方面進行，包括投資者角度觀點、結果測量的方法、研究資源的支援、處方的規範以及藥價控制等，乃至於不同文化、國情差異都應列入新藥給付時的考量。新藥上市前的階

段，對於建立公共政策針對新藥結果測量的一致性相當重要，特別是在方法學上選擇可比較的指標，注重研究計畫的補助以及平衡投資者收益的藥價機制等。特別是在全民醫療保險系統下的架構，提出能評價民眾自費之市場潛力及平衡支付方的另類策略。而藥廠則應針對於自費市場提出新藥價值更實際的成本效益分析。

參、 心得

世界製藥學術大會(PSWC, The Pharmaceutical Sciences World Congress) 屬於世界藥學會主辦之國際性會議，爲提供美、歐及世界各國製藥產、官、學界之醫藥研究資訊交流及教育的平台，並可了解國際藥學研究發展及製藥科技產業最新發展動向。

參加本次會議，體認到歐美各國對於製藥科學從基礎研究到藥品上市後之各領域之重視，尤以重視以實證爲基礎，發展出相關藥學資訊教育。包括藥品本身之品質的精益求精，病人服用藥物之效益評估，及上市後監測訂定相關控管機制等，由此點可說明，即使在健康醫療系統發展成熟的歐美先進國家，有關藥品安全性資訊仍未建立廣泛完整之機制。因此，加強有關安全性評估研究、不良反應資訊收集、跨學門整合研究、國際醫藥健康問題等，一再被大會不同演講者反覆提及，呼籲藥學研究者及政府單位應加強藥品發展各階段之安全性評估，並列入各國藥品政策及研發重點之推動方向。

反觀國內，在中藥管理的範疇內，行政院衛生署中醫藥委員會於

2001 年即成立中藥不良反應通報中心，藉由通報系統即時收集各類中藥不良反應相關資訊；包括申報醫院區域，病人服用藥物及症狀處置等。另於 2004 年完成我國中藥廠全面實施 GMP，將我國中藥廠統一輔導將製備品質提升，而我國全民健保制度自開辦之始，便將中藥納入醫療給付，相較於目前歐美各國因應天然健康食品發展之法規措施，我國政策更具先進與前瞻。

本會進一步於 2006 年爭取新興科技業務，開辦「中醫藥健康安全防護網」計畫，目標爲培訓中醫藥相關人才、研發創新、建置全球通路及就醫用藥安全的四項主軸下，推動生物技術與醫療之發展。內容包含：1、中藥有害物質背景值之收集與偵測系統之規劃建立。2、中藥材辨識資料背景值之收集與資料庫之規劃建置，推動資訊電子化。3、中醫藥產業產銷及進出口資訊、消費者、科技人才、法規等資料收集與資料庫建構，提供未來產學界與消費者使用。4、中醫診斷/治療基準之建立。5、中藥藥物毒理及指標/有效成分之研究與分析。中醫藥爲我國醫藥文化重要資源，也是我國發展生物科技產業的重點項目之一。本會扮演積極的角色，以中程計畫穩定支持相關科技研究發展經費，建立整體性、全面性的相關的技術、資訊與管理平台，健全醫藥發展環境及提昇醫療與藥品品質、以保障民眾就醫與用藥之安全爲目標。

藉由參與本次會議之經驗，透過專題演講瞭解目前國際醫療衛生及製藥學研各界之草藥及各類藥物最新研究開發趨勢外，特別觀察主辦單位辦理國際會議之方式，除了資源豐富，投入足夠的時間及人力

亦爲其成功主因，替與會者設想提供的各項軟硬體服務均值得借鏡參考。

肆、 建議事項

一、經由此次觀摩，深刻體認到我國中醫藥管理及研發等政策形成及推動，並不亞於其他國家，爲將我國經驗推廣至世界各國，並汲取先進國家科學化精髓，建議應積極派員參與各項相關國際會議，或以產、官、學、研代表共同組團方式參加，更可有效率達到合作契機，有助於提昇我國國際能見度，與各國專家學者作良好之互動，以建立日後交流互訪之基礎外，並可獲得更多藥學研發及法規最新動向等資訊，以掌握世界趨勢及培養國際觀。

二、爲因應我國加入 WTO 後，中藥相關政策法規應予評估制定，而國際間公認傳統醫藥在治療人類疾病上仍有許多發展空間，尤其中醫藥之臨床經驗爲各國尋求臨床發展之主要目標，因此建立國際協和化法規制度爲當務之急。94 年度已完成「中草藥新藥臨床試驗（IND）申請須知」及「中草藥新藥查驗登記（NDA）申請須知」之草案依程序公告外，應進行中醫藥法規與 WHO / WTO 協議協和化(harmonization)。以了解區域法規整合趨勢及對我國可能產生之影響，分析國際相關中藥法規趨勢及對我國可能產生之影響，統合國內法及國際法之差異，瞭解產、官、學、研各界對現行中藥法律在執行上、發展上之看法及意見，擬定適用我國之法規與基準意見，使我國中草藥之法規國際化、管理與全球一

致性，以利業者遵循，提昇我國製藥業之競爭力。

三、本會規劃中醫藥之科技研究重點，每年皆聘請產、官、學、研界菁英擔任科技諮詢委員，經召開數次諮詢會議，配合本會業務需要與工作目標，擬定研究重點，有系統的進行中醫藥相關科技研究計畫，期能藉由中醫藥科技發展，提昇中醫藥品質，提供科學化研究數據，以符合時代需求，促進國民健康。本會應積極加強與國外學研機構，例如美國 NCCAM 補助之各大學醫院 CAM 中心、英國 Exeter 大學、德國慕尼黑科技大學輔助療法研究中心等進行跨國性合作研究。使中醫藥藉由西方研究團隊，達到中醫藥全球化之目標。

四、有鑑於全球有一半的人口仰賴傳統醫學的醫療，WHO、美國FDA及歐盟陸續公佈對傳統醫學及中草藥相關法案及措施，而世界衛生組織（WHO）於2002.5.26發表『WHO Traditional Medicine Strategy 2002-2005』，並在世界衛生組織第56次大會中作成WHA56.31號決議，敦促會員國調整、採用和實施世界衛生組織的傳統醫學策略，對傳統醫學及中草藥產業之發展具有重大的意義。在世界衛生組織及各國致力推動傳統醫藥之際，爲確保國人用藥安全性及有效性，推動中醫藥科技蓬勃發展，順應世界潮流，在政府組織改造之際，建議應維持中醫藥委員會之專責機構，使民眾得到更優質的中醫藥服務，以利臺灣中醫藥發展，促進中醫藥現代化及國際化，並落實WHO 對傳統醫藥之全球策略。

伍、誌謝

非常感謝行政院衛生署中醫藥委員會提供經費補助，以及本會林主任委員宜信、羅主任秘書淑慧、陳組長崇哲及林高級研究員育娟支持並給予機會，使本出國計畫得以成行。參與此會議使報告人從國際會議中學習到許多珍貴經驗，並開拓國際視野，收穫良多。

陸、附錄

附錄一　PSWC 第三屆年會議程

附錄二　Huang WF et al., Cardiovascular events associated with long-term use of celecoxib, rofecoxib and meloxicam in Taiwan: an observational study. *Drug Safety*. 2006; 29(3):261-72.

THE SAFETY CONTROL PROGRAM OF HERBAL MEDICINE IN TAIWAN

Lee-Chin Chang, Tsui-Hsiu Kang, Yu-Chuan Lin, Chung-Tse Chen, Shu-Hui Lo, I-Hsin Lin

Committee on Chinese Medicine and Pharmacy, Department of Health, Taiwan

The Committee on Chinese Medicine and Pharmacy has implemented an investigational program for Chinese medicine to ensure the safety of the people. In the recent decades, there is an increasing trend in the utilization of herbal drugs worldwide. In Taiwan, traditional Chinese medicine is popular and co-exists with the modern Western medicine. Therefore, herbal drug safety is crucial to public health. In order to monitor herbal drug safety, the National Adverse Drug Reaction (ADR) Reporting System has been established since 2001. From 2001 to 2006, 701 cases were received by this system. The number of ADR cases increased dramatically from 13 in 2001 to 194 in 2006. Of these cases, 653 (93.2%) were reported by hospitals and 48 (6.8%) from the media press. These cases were divided into three broad categories: inappropriate herbal utilization (58.3%), herb-drug interactions (19.8%), and OTC herbal products (8.8%). Although the reported ADR cases are very limited, the true prevalence of immediate or chronic adverse effects causing by herbal medicines may be underestimated, since the majority of the cases were not reported. Nevertheless, information from this system may help to raise awareness of drug safety.

List of Research Projects Under The Safety Control Program

Category	The title of projects
Establishment of the herbal medicinal information database	1. Research and Development of Test Technique in Chinese herb harmful materials
	2. The collection and research on information of Chinese medicine identification
	3. Research for the harmful substance of traditional Chinese medicinal materials and examine technology information
	4. Study of mycotoxins contamination in traditional Chinese medicines
	5. Traditional Chinese medicinal materials distinguish the merger and management with consumer's information
	6. The harmful substance of traditional Chinese medicinal materials detects the merger and management of examining and detection technique research results
	7. Study on identification of common used Traditional Chinese medicine in Taiwan and the consumer inquires information
	8. The Production and Distribution of the Chinese Herbal Medicine, and its Integration Management Plan of the Import and Export Information
	9. Quality Control and Industrial Information Collection of Chinese Herbal Medicine
	10. Establishment and study of Chinese herbal medicine quality and producing and selling relevant information
	11. Identification and search information method on Chinese herbal medicine
	12. Traditional Chinese medicinal materials distinguish the merger and management of the result of study of the method
	13. Identification and search information method on Chinese herbal medicine
	14. Traditional Chinese medicinal materials distinguish the merger and management of the result of study of the method
	15. Talent Data Bank of science, technology and regulation of Traditional Chinese Medicine
Hepato- and Reno-toxicity studies for Herbal medicine	1. The pharmacoepidemiologic analysis of the suspected nephrotoxic prescriptions of finished herbal products
	2. Chinese Medicines Affect the Activity of Hepatic Metabolic Enzymes
	3. Studies on Hepatotoxicity and kidney toxicity of Chinese Herbal Medicines
	4. Studies on nephrotoxicity induced by ginseng, Lin-tsu (*Ganoderma lucidum*) and Ge-containing products
	5. Research on the functions of kidney influenced by the commonly used Chinese herbs-fuzi, wutou, tianxiong, banxia and dahuang
	6. Establishment of the aristolochic acid nephropathy in inbred mice and effect of *Bupleuri Radix*、Corydalis Tuber and Gee Gen Tong on the nephritis
	7. The analysis of the suspected nephrotoxic prescriptions of western medicines and Chinese herbs before dialysis in all dialysis patients in Taiwan
	8. Drug interaction of some commonly used traditional Chinese medicine and anti-cancer drug
	9. The benefit or risk of concurrent use with Chinese herb and western medicine — Effect of timimg of dosing
	10. Studies on the interactions between traditional Chinese Medicines and aspirin-like drugs on hepatic and renal functions of the mice
	11. Short-term and long-term administration of concentrated compound Chinese herbal medicine—drug interaction studies in animal
	12. To investigate the synergic effect of *Angelicae sinensis* extract with current chemotherapy in human hepatocellular carcinoma
	13. The effects and mechanism studies of herb drugs combining with western medicine to inhibit liver fibrosis in animal models
	14. A population-based study on co-prescription patterns of Chinese and Western medicines in Taiwan
	15. Exploration of the safety of concurrent use of herbs with western medicine
	16. The effect of concentrated compound Chinese herbal medicine drug on toxicity studies in kidney
	17. Evaluation of the efficacy and the associated toxicity induced by Western medicine and traditional Chinese medicine combination on the diabetic nephropathy
R & D research for herbal medicine (Q.C. studies included)	1. Research & Development of Chinese herb active fraction, reference standard and index fraction
	2. The preparations of Chinese herbal standard, gentianine, honokiol and wogonin, and the studies of their examing methods.
	3. Research on the developmemt and the analysis of ferulic acid and ligustilide, the Chinese herbal standards
	4. The development and Detection technique of paeoniflorin and paeonol reference standard of Chinese Herbal Medicines
	5. Feasibility of Chinese herbs medicine as feed additives for chicken
	6. Study on the culture techniques and anti-tumor activities of *Antrodia cinnamomea*
	7. Studies on the application of Chinese herbal medicines on cosmetic additives
	8. Study on the Chinese medicine herb added in cosmetics and evaluate their safety and effectiveness
	9. Evaluation of the species of crops for healthy and medicinal purpose suitable To cultivating in the Eastern area of Taiwan
	10. Investigation and Study on the culture of Chinese medicinal herb in Taiwan (II)
	11. Evaluation and analysis on the output value of Chinese herbs
	12. Cultivation evaluation of suitable medicinal plants in North, Middle, and South parts of Taiwan
	13. Establishment and study of Chinese herbal medicine quality and producing and selling relevant information
	14. Investigation and study of impurity guidelines form natural medicinal products
The Diagnostic criteria establishment for Traditional Chinese Medicine	1. The study of Chinese medical constitution in cardiac vascular surgery patient by HRV and APACHE
	2. The operational procedure for symptoms and signs in traditional Chinese medicine
	3. The evidence based study of Chinese medicine treatment in attention deficiency hyperactive disorder
	4. The study on Chinese medicine pattern of post-stroke dementia and the relationship between pattern and severity of dementia
	5. Application of Dan-Chi-Liu-Wei combination in SLE patients to taper steroid and to prevent disease flare
	6. Studying of the characteristic of the different Symptoms(證) of endometriosis according the Chinese medical differential diagnosis
	7. Study On The Scientific Diganosis Standard For Chinese Traunatology
	8. The Standard Diagnostic Procedure For Qi-Vacuity in TCM
	9. Power spectral analysis of radial artery pulse waveform (II)
	10. Study of distribution of Chinese herbs for prevention of preterm labor in maternal blood, placenta and umbilical cord blood
	11. The training program of the evidence-based traditional ChinesemMedicine
	12. Development of five Zang constitutional scale of traditional Chinese medicine

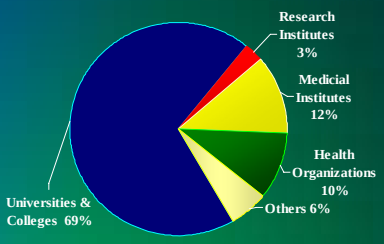
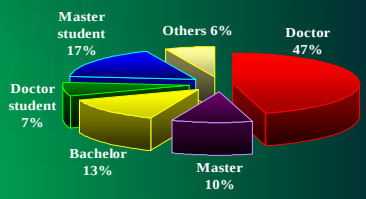


Fig.1 Performance Sectors Analysis

Fig. 2 Manpower Analysis



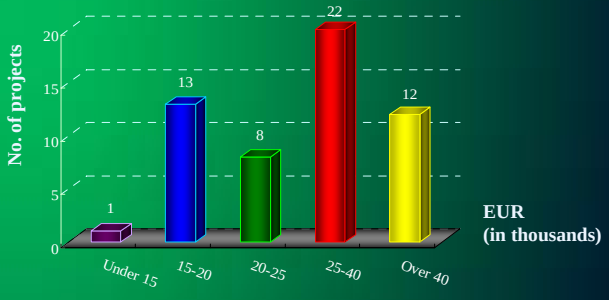


Fig.3 Budget Allocation

Conclusion

From 2006, the 56 projects are carried out to clarify unclear aspects of herbal medicines by evidence-based research in the safety control program. A total of 340 experienced scientific investigators including 90 (26.5%) clinicians participate in this program. The program consists of R&D research for herbal medicine (30%), evaluation of safety and toxicity (26%), establishment of the diagnostic criteria in Chinese medicine (19%), and setting up of database related to herbal species and impurities for consumers and industries (14%). Professional training courses and international conference to Chinese medicine are also implemented. This program not only improves the quality of herbal drug safety but also provides educational opportunities for the practitioners.

Committee on Chinese Medicine and Pharmacy, Department of Health, Taiwan

Add: No.6,Shuangcheng St., Jhongshang District, Taipei City, 10453 Taiwan
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PSWC 2007

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FINAL PROGRAMME

附錄一

Pharmaceutical Sciences World Congress

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Dear Colleague

A warm welcome to the Third World Congress of the Board of Pharmaceutical Sciences of FIP (Fédération Internationale Pharmaceutique or International Pharmaceutical Federation).

The new millennium in 2000 saw the staging of the First Pharmaceutical Sciences World Congress (PSWC2000) in San Francisco, bringing together 2,500 pharmaceutical scientists from around the world. The Second Congress, also with a truly global span, was held in the Spring of 2004 in Kyoto, Japan (PSWC2004), and attracted even more participants. The ***Third*** *Congress is now to convene in Amsterdam (PSWC2007) with the theme of:*

Optimising Drug Therapy: An Imperative for World Health

The program committee, chaired by renowned pharmaceutical scientists, has ensured excellence in scientific quality and a high visibility for the conference. Like the previous two conferences, PSWC2007 will cover a broad spectrum of topics from basic to applied and clinical sciences, addressing timely issues of great importance to drug discovery, development, regulation, and medication management. It will also feature interactive round table discussions, poster sessions, a career centre and an exhibition, and will devote significant attention to young pharmaceutical scientists through poster and podium presentations as well as a pre-conference meeting for graduate students and post-doctoral fellows.

PSWC2007 is co-sponsored by many of the world's leading pharmaceutical science and education organisations and members of the FIP, including the European Federation for Pharmaceutical Sciences, EUFEPS, the American Association of Pharmaceutical Scientists, AAPS, the Australasian Pharmaceutical Science Association, APSA, the Academy of Pharmaceutical Sciences of Great Britain, APSGB, the Association de Pharmacie Galénique Industrielle, APGI, the Academy of Pharmaceutical Sciences and Technology, Japan, APSTJ, the Controlled Release Society, CRS, the Pharmaceutical Society of Japan, PSJ, and the Spanish Society of Pharmaceutics and Pharmaceutical Technology (SSPPT). In addition, an impressive number of other organisations have pledged their active (financial) support, and they are listed under supporting or sponsoring organisations elsewhere in the programme.

Over 1250 abstracts have been submitted by registrants from 70 countries. In total, PSWC2007 will offer close to 1500 presentations!

Apart from the main 36 symposia, 4 satellite meetings have been organised under the aegis of PSWC2007. These are:

Two pre-satellite meetings:

- *As already mentioned, a meeting especially for* ***Ph.D. students and Postdocs*** *(co-sponsored by a number of organisations)*
- *A workshop on* ***Pharmacy Curriculum Development*** *(organised by Utrecht University)*

Two post-satellite meetings:

- *A meeting on* ***Monoclonal Antibodies*** *(co-sponsored by EUFEPS/EAPB/FIP/AAPS)*
- *A symposium on* ***Microdialysis*** *(Leiden University/FIP/EUFEPS)*

And, finally,

- ***The Mid Year Meeting 2007 of ISPE****, the International Society for Pharmacoepidemiology, which partly overlaps with PSWC2007.*

Everything is set for a highly exciting event and an important forum for the global community of pharmaceutical scientists!

The co-chairs forming the PSWC2007 Organising Committee, the Scientific Advisory Board and the leadership of FIP's Board of Pharmaceutical Sciences welcome you to this Third Pharmaceutical Sciences World Congress (PSWC2007) in Amsterdam, one of the most colourful cities in the world!

On behalf of the PSWC2007 Co-chairs of the Organising Committee,

Daan J. A. Crommelin, Ph.D.
Chair of the Organising Committee

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Y. Sugiura, Japan
M. Shibasaki, Japan
T. Sonobe, Japan
A. Ichikawa, Japan
H. Terada, Japan
E. Kimura, Japan
K. Inoue, Japan
T. Nagai, Japan
T. Kawasaki, Japan
T. Mayumi, Japan
T. Kimura, Japan
M. Hayashi, Japan
K. Yamamoto, Japan
M. Otagiri, Japan
A. Tsuji, Japan
Y. Kawashima, Japan
T. Honda, Japan
I. Kudo, Japan
Y. Ebizuka, Japan
T. Nagano, Japan
Y. Kirino, Japan
H. Natsugari, Japan
T. Kamataki, Japan
Y. Yamazoe, Japan
H. Sugimoto, Japan
K.-I. Inui, Japan
J.-I. Goto, Japan
T. Iga, Japan
H. Suzuki, Japan
M. Uchiyama, Japan
T. Ozawa, Japan
T. Kobayashi, Japan
T. Nakanishi, Japan
H. Zenda, Japan
K. Nishimura, Japan
S. Morimoto, Japan
T. Takayanagi, Japan
K. Saito, Japan
E. Murayama, Japan
M. Odomi, Japan
S. Kubo, Japan
M. Toda, Japan
M. Ishiguro, Japan
T. Oguma, Japan
Y. Yasuda, Japan
T. Sawayama, Japan
T. Naka, Japan
H. Yoshino, Japan
R. Konishi, Japan
R. Ibuki, Japan
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PSWC2007 Registration Support for PhD Students and Young Postdocs

Belgian Society for Pharmaceutical Sciences (BSPS)
Dutch Federation of Pharmaceutical Sciences (NVFW)
German Pharmaceutical Society (DPhG)

Day	Time	Activity	Place
Sunday, April 22, 2007	10:00-17:00	Registration	Forum Foyer
	10:00-17:00	Press/Speakers Room	Room M 1st floor Forum Part
	09:00-18:00	Career Centre	Rooms F&G 1st floor Auditorium Part
	09:00-18:00	Career Centre	Commission 1 ground floor Auditorium Part
	15:00-17:30	Opening Session	Main Auditorium
	17:30-19:00	Welcome Reception	Hall 10 st floor Forum Part
Monday, April 23, 2007	07:30-08:30	Hang up Posters	Hall 10 st floor Forum Part
	08:00-17:00	Registration	Forum Foyer
	09:00-17:00	Exhibition & Posters	Hall 10 st floor Forum Part
	09:00-17:00	Press/Speakers Room	Room M 1st floor Forum Part
	09:00-18:00	Career Centre	Rooms F&G 1st floor Auditorium Part
	09:00-18:00	Career Centre	Commission 1 ground floor Auditorium Part
	11:15-12:15	Authors at Poster Board	Hall 10 st floor Forum Part
	17:00-18:00	Take down Posters	Hall 10 st floor Forum Part
	18:00-19:00	Put up New Poster Numbers	Hall 10 st floor Forum Part
Tuesday, April 24, 2007	07:30-08:30	Hang up Posters	Hall 10 st floor Forum Part
	08:00-17:00	Registration	Forum Foyer
	09:00-17:00	Exhibition & Posters	Hall 10 st floor Forum Part
	09:00-17:00	Press/Speakers Room	Room M 1st floor Forum Part
	09:00-18:00	Career Centre	Rooms F&G 1st floor Auditorium Part
	09:00-18:00	Career Centre	Commission 1 ground floor Auditorium Part
	11:15-12:15	Authors at Poster Board	Hall 10 st floor Forum Part
	17:00-18:00	Take down Posters	Hall 10 st floor Forum Part
	18:00-19:00	Put up New Poster Numbers	Hall 10 st floor Forum Part
Wednesday, April 25, 2007	07:30-08:30	Hang up Posters	Hall 10 st floor Forum Part
	08:00-14:30	Registration	Forum Foyer
	09:00-14:30	Exhibition & Posters	Hall 10 st floor Forum Part
	09:00-14:30	Press/Speakers Room	Room M 1st floor Forum Part
	09:00-18:00	Career Centre	Rooms F&G 1st floor Auditorium Part
	09:00-18:00	Career Centre	Commission 1 ground floor Auditorium Part
	11:15-12:15	Authors at Poster Board	Hall 10 st floor Forum Part
	14:00-14:30	Take down Posters	Hall 10 st floor Forum Part

Programme Time Schedule	
6 Parallel Symposia & Events	
Speaker Presentation	08:30 – 09:05
Speaker Presentation	09:05 – 09:40
Break 09:40 – 10:10	
Speaker Presentation	10:10 – 10:45
Podium Presentations	10:45 – 11:15
Lunch Poster Session	
Keynote Presentations	12:15 – 13:00
Round Table Discussion	13:10 – 14:10
Speaker Presentation	14:15 – 14:50
Speaker Presentation	14:50 – 15:25
Speaker Presentation	15:25 – 16:00
Podium Presentations	16:00 – 16:30
Break 16:30 – 16:45	
EUFEPS Afternoon Sessions	16:45 – 18:15

Congress Reception

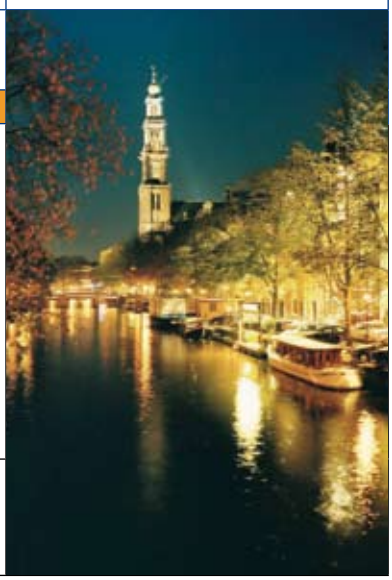
The Welcome Reception is planned on Sunday, April 22, 2007, right after the Opening Session together with the Opening of the PSWC2007/PharmSciFair Exhibition in Hall 10 of the RAI Convention and Exhibition Centre for all participants and accompanying persons.

Congress Dinner

The Congress Dinner on Tuesday, April 24, 2007, will take place at the famous Wintergarden of the Krasnapolsky Hotel, Dam 9, in the Centre of Amsterdam: 20:00-22:30 hours.

Tickets (Euro 90 including VAT) are limited in number (first-come, first-served). For tickets contact the Registration Desk.

Programme at a Glance

Scientific Programme Overview • April 22-25 • 2007			
Sunday	**Monday**	**Tuesday**	**Wednesday**
Registration	Parallel Symposia ■ The era of personalised health care: Impact on drug discovery and development? ■ Is gene/protein delivery delivering? ■ Can ADME and PK be predicted from *in silico/in vitro* data? ■ Metabolomics: What are the opportunities for biomarker discovery? ■ What benefits does Process Analytical Technology (PAT) bring to the design and assurance of product quality? ■ What have we learnt from recent safety cases for new drug development?	Parallel Symposia ■ Druggability: A concept that will fill the pipeline? ■ Drug targeting: How successful are we? ■ What is the state-of-the-science in receptor site modelling? ■ What's new in methods of measuring human drug response? ■ *In silico* product development from molecule to man: Dream or reality? ■ Nutraceuticals: Are new methods of evaluating risk/benefit required?	Parallel Symposia ■ How to manage drug therapy at the extremes of age? ■ How can nanotechnology and materials science solve drug delivery problems? ■ How important is genetic and physiological variability in drug transporters? ■ Systems biology: A driver of drug discovery and development? ■ How to engineer desired particle properties for drug delivery? ■ Off-label use of medicines: Abuse or a vehicle for innovation?
	Posters & Exhibition & Lunch		
Opening Session	Keynote Presentations ■ What are the main challenges for world health? What should be done now and in the future? ■ Transforming 'art' into 'science' in dosage form design – achievements and challenges	Keynote Presentations ■ Are we meeting the challenges of resistance to anti-infective drugs and of newly emerging infectious diseases? ■ Will novel approaches to the treatment of cardiovascular disease prove highly effective?	Keynote Presentations ■ Drug resistance in cancer chemotherapy ■ Recent progress in prion biology
	Round Table Discussions ■ Science or business as the driver of new drug development? ■ Does regulation help to 'innovate' or 'stagnate' drug development? ■ How can the bioavailability of poorly absorbed compounds be enhanced?	Round Table Discussions ■ Translational science: A solution to the productivity gap? ■ Can microdosing accelerate drug development? ■ When is a human bioequivalence study not needed?	Round Table Discussions ■ What is the value of observational data post-marketing to assess safety and efficacy? ■ Life-style drugs: A new burden to the health system? ■ Is there a consensus on guidelines for the evaluation of biosimilars?
	Parallel Symposia ■ Pharmacogenetics at the bedside? ■ What will be the impact of cell-based therapy? ■ Simulation and modelling in drug development improves decisions, saving time and money? ■ Dirty vs. selective drugs in the CNS? ■ How will developments in chemical methods sustain pharmaceutical industrial development? ■ How effective is the globalisation/harmonisation of pharmacovigilance?	Parallel Symposia ■ Drug-drug interactions: Avoid or understand? ■ What is the future of smart, feedback, on-demand drug delivery systems? ■ How are disease and PK-PD connected? ■ Have omics technologies improved the chance for successful drug development? ■ Are pharmaceutical manufacturing technologies in stagnation? ■ Are we using the right outcome measures to ascertain patient benefit from drug therapy?	Parallel Symposia ■ Is the patient taking the tablets? ■ Developing biotech products: What are the challenges and solutions? ■ Control of intracellular pharmacokinetics: Advantages for drug therapy? ■ Molecular targeting in cancer chemotherapy? ■ Miniaturisation in analytical methods: Is small always beautiful? ■ Counterfeiting of medicines: Detection and prevention?
	Round Table Discussion ■ Proactive risk management (plans): Where are we?		
	Short Break		
	EUFEPS Afternoon Sessions ■ Strategic, innovative and critical drug research initiatives: One year later ■ Pharmaceutical sciences research training and education: Needs and supply ■ The EU Microdosing AMS Partnership Programme (EUMAPP) ■ The European Pharma Sciences Leadership Forum (EuPSLF) ■ Pharmaceutical sciences *in silico* learning systems: Value and availability	EUFEPS Afternoon Sessions ■ European drug development centres and European growth areas ■ Reformulation of old drugs: Life cycle management ■ Vaccine delivery ■ PharmacoGenetics & PharmacoGenomics Workshop: Outcomes and plans ■ How to start up a new company? ■ Drug product quality after new legislation	
Exhibition Opening and Welcome Reception		Congress Dinner	

SCIENTIFIC PROGR

	Parallel Symposium Room: Auditorium The era of personalised health care: Impact on drug discovery and development? Sponsoring Organisation	Parallel Symposium Room: Forum Is gene/protein delivery delivering? Sponsoring Organisation	Parallel Symposium Room: N-O Can ADME and PK be predicted from *in silico/ in vitro* data?
	Co-chairs *M. E. Brewster*, Beerse, Belgium *W. Sadee*, Columbus, OH USA *Y. Sugiyama*, Tokyo, Japan	Co-chairs *H. Harashima*, Sapporo, Japan *W. Hennink*, Utrecht, The Netherlands	Co-chairs *S. Pang*, Toronto, Canada *H. van de Waaterbeemd*, Alderly Park, United Kingdom
08:30	Evaluating molecular genetic factors in drug response: Search for drug targets and biomarkers *W. Sadee*, Columbus, OH USA	A multi-functional envelope type nano device as a non-viral gene delivery system *H. Harashima*, Sapporo, Japan	Translation of *in vitro* data to the whole organ *S. Pang*, Toronto, Canada
09:05	Predicting drug disposition and response in individual patients: Role of drug transporters for influx and efflux processes *Y. Sugiyama*, Tokyo, Japan	Cellular mechanisms of non-viral DNA delivery *A. Urtti*, Helsinki, Finland	*In vitro – in vivo* extrapolation: Best use of known-knowns to discover unknown-unknowns *A. Rostami-Hodjegan*, Sheffield, United Kingdom
09:40	**Coffee Break**		
10:10	Biomarkers in drug development: How do they influence clinical practice? *L.J. Lesko*, Silver Spring, MD USA	Intravenous siRNA for silencing target genes in solid tomor *L. Huang*, Chapel Hill, NC USA	A computational systems biology approach to ADME/Tox S. *Ekins*, New York, NY USA
10:45	Pharmacogenomic analysis reveals determinants of sensitivity and resistance to geldanamycin analogues: Role of membrane transporters *Y. Huang*, Pomona, USA (MO-S01-1)	Silencing of SOCS genes in cancer cells for effective interferon cancer therapy: Enhancement of antitumor activity of interferons by rnai-mediated silencing of socs gene expression *Y. Takahashi*, Kyoto, Japan (MO-S02-1)	Assessment of computational and *in vitro* methods as predictors of oral drug absorption *M. Yliperttula*, Helsinki, Finland (MO-S03-1)
11:00	Pharmacogenetics: From research results to practical guidelines *L. Grandia*, The Hague, The Netherlands (MO-S01-2)	Gene expression and silencing for improved islet transplantation *R. Mahato*, Memphis, USA (MO-S02-2)	Volume of distribution predictions: understanding the processes *T. Rodgers*, Manchester, United Kingdom (MO-S03-2)
11:15	**Posters** **Lunch Break**		
	Keynote Presentation **Room: Auditorium**	**Keynote Presentation** **Room: Forum**	
	Chair *H. Leufkens*, Utrecht, The Netherlands	Chair *M. Hashida*, Kyoto, Japan	
12:15	What are the main challenges for world health? What should be done now and in the future? *R. Laing*, Geneva, Switzerland (KLM-1)	Transforming 'art' into 'science' in dosage form design – achievements and challenges *P. York*, Bradford, United Kingdom (KLM-2)	
	Round Table Discussion **Room: L**	**Round Table Discussion** **Room: A**	**Round Table Discussion** **Room: C-D**
13:10	Science or business as the driver of new drug development? Convenor *L.Z. Benet*, San Francisco, CA USA	Does regulation help to 'innovate' or 'stagnate' drug development? Convenor *L.J. Lesko*, Silver Spring, MD USA	How can the bioavailability of poorly absorbed compounds be enhanced? Convenor *C.-M. Lehr*, Saarbrücken, Germany
	Parallel Symposium **Room: Auditorium** Pharmacogenetics at the bedside?	**Parallel Symposium** **Room: N-O** What will be the impact of cell-based therapy?	**Parallel Symposium** **Room: Forum** Simulation and modelling in drug development improves decisions, saving time and money? Sponsoring Organisation
	Co-chairs *G.T. Tucker*, Sheffield, United Kingdom *M. Schwab*, Stuttgart, Germany	Co-chairs *E. Cattaneo*, Milan, Italy *S. Nakagawa*, Osaka, Japan	Co-chairs *D. Stanski*, Basel, Switzerland/East Hanover, NJ USA *M. Danhof*, Leiden, The Netherlands
14:15	Pharmacogenetics – how far is reality from expectation? *G.T. Tucker*, Sheffield, United Kingdom	Innovative neurogenic neural stem cell lines for neurodegenerative disease *E. Cattaneo*, Milan, Italy	Applying mechanistic pharmacokinetic-pharmacodynamic (PK/PD) models to drug development *M. Danhof*, Leiden, The Netherlands
14:50	Multiple gene pharmacogenetics in individualized drug therapy *I. Ieri*, Yonago, Japan	Cancer immunotherapy using gentically modified denritic cells *S. Nakagawa*, Osaka, Japan	Examples of modelling and simulation in the pharmaceutical industry *C. Pillai*, Basel, Switzerland
15:25	Pharmacogenetics in cancer therapy *M. Schwab*, Stuttgart, Germany	Cardiac regeneration: Repopulating the heart *L.J. Field*, Indianapolis, IN USA	The role of innovative model-based trial design to improve drug development *S. Duffull*, Dunedin, New Zealand
16:00	Pharmacogenetics in paediatric drug development and utilisation: Are we going in the right direction? *E. H. J. Krekels*, Leiden, The Netherlands (MO-S07-1)	A study of cell cycle and stem cell markers to identify the factors responsible for cardiac regeneration in mrl mice *F. Moseley*, Reading, United Kingdom (MO-S08-1)	Using pharmacokinetic-pharmacodynamic analysis in drug discovery. An example on the integration of mechanistic, principle and conceptual effect markers. *S. Visser*, Seodertaelje, Sweden (MO-S09-1)
16:15	The association of warfarin dosage in clinical use and pharmacogenomics *Y.-H. Chen*, Taipei, China Taiwan (MO-S07-2)	Alteration of endothelial cell function under high-glucose condition: Association with both disruption of cell-to-cell connection and non-muscle contraction *K. Nobe*, Tokyo, Japan (MO-S08-2)	Quantification of alpha 1-adrenoceptor concentration, ligand binding kinetics and inotropic response in the perfused rat heart: a PK/PD modeling analysis *P. Sermsappasuk*, Halle (Saale), Germany (MO-S09-2)
16:45-18:15	**EUFEPS Afternoon Sessions** *See pages 18-20*		

AMME • Monday

	Parallel Symposium Room: L Metabolomics: What are the opportunities for biomarker discovery?	Parallel Symposium Room: C-D What benefits does Process Analytical Technology (PAT) bring to the design and assurance of product quality?	Parallel Symposium Room: A What have we learnt from recent safety cases for new drug development? ISPE Midyear Symposium
	Co-chairs *T. Hankemeier*, Leiden, The Netherlands *I. Schuppe-Koistinen*, Soedertaelje, Sweden	Co-chairs *S. Folestad*, Moelndal, Sweden *J. Pritchard*, Loughborough, United Kingdom	Co-chairs *H. Leufkens*, Utrecht, The Netherlands *M Sturkenboom*, Rotterdam, The Netherlands
08:30	Systems biology & metabolomics: How far are we? *T. Hankemeier*, Leiden, The Netherlands	Real-time prediction and control of quality – the mechanistic approach to PAT *S. Folestad*, Moelndal, Sweden	A pharmaco-epidemiological reflection on recent drug safety cases *A. Walker*, Boston, MA USA
09:05	The application of metabolic profiling technologies in biomarker discovery during drug R&D *I. Schuppe-Koistinen*, Soedertaelje, Sweden	The benefits of PAT in ICH and Japanese regulation *Y. Hiyama*, Tokyo, Japan	Class effects in drug safety and management *H. Leufkens*, Utrecht, The Netherlands
09:40	**Coffee Break**		
10:10	Metabolomics by CE-MS for biomarker discovery *T. Soga*, Tsuruoka, Japan	Benefits of PAT for bioprocesses: Process design and quality assurance at the example of fermentation processes for recombinant protein production *A. Luebbert*, Halle, Germany	Industry responding to learning from safety cases *S. Perez-Gutthann*, Barcelona, Spain
10:45	A novel immunoassay for monitoring caffeine as an environmental marker for pharmaceuticals input *J. J. Carvalho*, Berlin, Germany (MO-S04-1)	Evaluation of in-line near infrared spectroscopy for predicting tablet content uniformity during powder mixing *H. M. J. Salokangas*, Espoo, Finland (MO-S05-1)	Influence of COX-inhibitors on blood-brain barrier properties *B. Germann*, Vienna, Austria (MO-S06-1)
11:00	Metabolomic approach for QA/QC on TCM material medica processing procedures-using citrus reticulata as the sample *W.-T. Chang*, Taichung, China Taiwan (MO-S04-2)	Raman spectroscopy as a PAT in tablet manufacturing *A. Sakr*, Cincinnati, USA (MO-S05-2)	Monitoring on drug-induced hepatopathy and granulocytopenia using hospital database resources: Prescription and laboratory data linkage *J. Kawakami*, Hamamatsu, Japan (MO-S06-2)
11:15	**Posters** **Lunch Break**		
	Parallel Symposium Room: L Dirty vs selective drugs in the CNS? Sponsoring Organisation: Solvay Pharmaceuticals	Parallel Symposium Room: C-D How will developments in chemical methods sustain pharmaceutical industrial development?	Parallel Symposium Room: A How effective is the globalisation/ harmonisation of pharmacovigilance? Endorsing Organisation: CBG MEB
	Co-chairs *H. Meltzer*, Nashville, TN USA *C. Sennef*, Weesp, The Netherlands	Co-chairs *T. Ohwada*, Tokyo, Japan *U. Holzgrabe*, Wuerzburg, Germany	Co-chairs *F. Lekkerkerker*, The Hague, The Netherlands *M. Braun*, Rockville, MD USA
14:15	Rational polypharmacy within a single molecule: The basis for current antipsychotic treatment *H. Meltzer*, Nashville, TN USA	Process chemistry as leverage for drug development and profitability in the pharmaceutical industry *T. Konoike*, Amagasaki, Japan	The science underlying the practice of pharmacovigilance *N. Moore*, Bordeaux, France
14:50	The treatment of major depression: Single or multiple target? *F. Artigas*, Barcelona, Spain	Active targeting of anticancer agents: Chemical aspects of folate-drug conjugate design *I. Vlahov*, West Lafayette, IN USA	International variety in interpretation and management of drug safety *N. Wathion*, London, United Kingdom
15:25	Muscarinic receptors as a target in the treatment of disorders of the CNS: Antagonism, agonism or both? *B. Dean*, Melbourne, Australia	The synthetic development of the anti-influenza neuraminidase inhibitor oseltamivir phosphate (Tamiflu®): A challenge for synthesis and process research *M. Karpf*, Basel, Switzerland	ICH, CIOMS, ISOP, ISPE and other acronymic vehicles to enable harmonisation of pharmacovigilance *C-K. Shim*, Seoul, South Korea
16:00	Learning and memory impairments in congenic C57BL/6NTac mice that lack the m2 muscarinic acetylcholine receptor subtype C. Wrenn, Des Moines, USA (MO-S10-1)	Random chemistry as a new tool for the generation of small-compound libraries *U. Holzgrabe*, Wuerzburg, Germany (MO-S11-1)	**Round Table Discussion**
16:15	Neuronal protective effect of recombinant arginine deiminase in a nitric oxide overexpression cell culture system H.-H. Yu, Taipei, China Taiwan (MO-S10-2)	Generation and application of o-benzoquinone methides bearing various substituents on the benzene ring *T. Ohwada*, Tokyo, Japan (MO-S11-2)	Proactive risk management (plans): Where are we? Convenor *F. Lekkerkerker*, The Hague, The Netherlands
16:45-18:15	**EUFEPS Afternoon Sessions** *See pages 18-20*		

	Parallel Symposium **Room: Forum** Druggability: A concept that will fill the pipeline? Sponsoring Organisation 	**Parallel Symposium** **Room: Auditorium** Drug targeting: How successful are we?	**Parallel Symposium** **Room: N-O** What is the state-of-the-science in receptor site modelling?
	Co-chairs *D. Nicholson*, Oss, The Netherlands	Co-chairs *M. Hashida*, Kyoto, Japan *R. Duncan*, Cardiff, United Kingdom	Co-chairs *S. Dahl*, Tromsoe, Norway *M. Ishiguru*, Osaka, Japan
08:30	Druggability and the concept of ADME space *D. Smith*, Sandwich, United Kingdom	Drug and gene delivery by combination of ultrasound and bubble liposomes *K. Maruyama*, Kanagawa, Japan	Genomics to drug targets by molecular modelling *S. Dahl*, Tromsoe, Norway
09:05	Drugability and drug-likeness: A medicinal chemist's view *B. Testa*, Lausanne, Switzerland	Polymeric conjugates as anticancer nano-medicines: Mechanism of action and drug combinations *R. Duncan*, Cardiff, United Kingdom	Functional structural models of G protein coupled receptors *M. Ishiguru*, Osaka, Japan
09:40	**Coffee Break**		
10:10	Concave druggability of protein surfaces for accelerating *in silico* screening *H. Shirai*, Tsukuba, Japan	Targeting with molecularly decorated nano-particles *N. Peppas*, Austin, TX USA	Structure-based virtual screening *J. Irwin*, San Francisco, CA USA
10:45	Predicting druggable proteins from amino acid sequence by a machine learning approach *C.W. Yap*, Singapore, Singapore (TU-S01-1)	Prevention of cytokines responses in cardiac allograft rejection by systemic injection of nf-kappa B decoy/mannosylated cationic lipo-some complexes *Y. Higuchi*, Kyoto, Japan (TU-S02-1)	Identification of a conserved hydrophobic asparagine-cage as a constraint for family a GPCR activation *A. Jongejan*, Amsterdam, The Netherlands (TU-S03-1)
11:00	Medicinal chemistry of hERG optimisations *E. Moir*, Newhouse, United Kingdom (TU-S01-2)	Squalenoylated-gemcitabine nanomedi-cine exhibits potential in cancer therapy at preclinic *H. R. Lakkireddy*, Châtenay-Malabry, France TU-S02-2)	Delineating a powerful virtual screening protocol for G-protein coupled receptors: Application to selective kappa opioid receptor agonist, salvinorin a *N. Singh*, Mississippi, USA (TU-S03-2)
11:15	**Posters** **Lunch Break**		
	Keynote Presentation **Room: Auditorium** Sponsoring Organisation 	**Keynote Presentation** **Room: Forum** Sponsoring Organisation Solvay Pharmaceuticals 	
	Chair *W. Sadee*, Columbus OH USA	Chair *C. Senneff*, Weesp, The Netherlands	
12:15	Are we meeting the challenges of resistance to anti-infective drugs and of newly emerging infectious diseases? *L. Schlesinger*, Columbus OH USA (KLT-1)	Will novel approaches to the treatment of cardiovascular disease prove highly effective? *J. Kastelein*, Amsterdam, The Netherlands (KLT-2)	
	Round Table Discussion **Room: A** Sponsoring Organisation 	**Round Table Discussion** **Room: L**	**Round Table Discussion** **Room: C-D**
13:10	Translational science: a solution to the pro-ductivity gap? Convenor *D. Nicholson*, Oss, The Netherlands	Can microdosing accelerate drug develop-ment? Convenor *A. Grahnen*, Uppsala, Sweden	When is a human bioequivalence study not needed? Convenor *L.Z. Benet*, San Francisco, CA USA
	Parallel Symposium **Room: A** Drug-drug interactions: Avoid or understand?	**Parallel Symposium** **Room: N-O** What is the future of smart, feed-back, on-demand drug delivery systems?	**Parallel Symposium** **Room: Forum** How are disease and PK-PD connected?
	Co-chairs *K. Thummel*, Seattle, WA USA *A. McLachlan*, Sydney, Australia	Co-chairs *J. Kopecek*, Salt Lake City, USA *K. Kataoka*, Tokyo, Japan	Co-chairs *Y. Tanigawara*, Tokyo, Japan *R. Bruno*, Mountain View, CA USA
14:15	Managing herb-drug interactions: Under-standing mechanism and educating the public *A. McLachlan*, Sydney, Australia	Smart drug delivery systems: State-of-the-art and future directions *J. Kopecek*, Salt Lake City, USA	Bone disease progression and drug action *N. Holford*, Auckland, New Zealand
14:50	Role of the pharmacist in avoiding drug-drug interactions with patient self-care *E. Nakashima*, Tokyo, Japan	Light-induced gene and drug delivery by supramolecular nanocarrier *K.Kataoka*, Tokyo, Japan	Mechanism-based modelling of disease pro-gression – disease system analysis *B. Ploeger*, Leiden, The Netherlands
15:25	Application of a drug-drug interaction data base in drug development and clinical educa-tion *K. Thummel*, Seattle, WA USA	Smart polymeric carriers for biomolecular drugs *P. Stayton*, Seattle, WA USA	Modelling of cancer progression and drug effects *R. Bruno*, Mountain View, CA USA
16:00	Sfinx – construction and implementation of a novel drug drug interaction database *B. Eiermann*, Stockholm, Sweden (TU-S07-1)	Transdermal iontophoresis of dopamine ago-nist 5-OH-DPAT: Correlation of in vitro trans-port to the integrated pk-pd profiles based on non-linear mixed effect modeling *A. K. Nugroho*, Yogyakarta, Indonesia (TU-S08-1)	Pharmacokinetic-pharmacodynamic model for propofol during long-term sedation in the critically ill patient *M. Peeters*, Nieuwegein, The Netherlands (TU-S09-1)
16:15	Can we predict the magnitude of drug-drug interaction in a simple way?: Simulation of interaction of rapidly-eliminating drugs with fluvoxamine by dynamo-pk analysis method *K. Iga*, Kyotanabe, Japan (TU-S07-2)	Biodegradable microparticles containing dexamethasone and spions for intra-articular delivery *N. Butoescu*, Geneva, Switzerland (TU-S08-2)	Population pharmacokinetic modelling of radioiodine turnover in patients with Graves' disease *I. Grabnar*, Ljubljana, Slovenia (TU-S09-2)
16:45-18:15	**EUFEPS Afternoon Sessions** *See pages 18-20*		

AMME • Tuesday

	Parallel Symposium **Room: A** What's new in methods of measuring human drug response? Sponsoring Organisation 	**Parallel Symposium** **Room: C-D** *In silico* product development from molecule to man: Dream or reality?	**Parallel Symposium** **Room: L** Nutraceuticals: Are new methods of evaluating risk/benefit required?
	Co-chairs *A. Cohen*, Leiden, The Netherlands *P. Macheras*, Athens, Greece	Co-chairs *P. York*, Bradford, United Kingdom *V. Venkatasubramanian*, West Lafayette, IN USA	Co-chairs *H. Ohama*, Tokyo, Japan *R. Oledzka*, Warsaw, Poland
08:30	The data intensive first administration to man study – functional outcome replaces tolerability: The impact of new measurement techniques *A. Cohen*, Leiden, The Netherlands	Structure, thermodynamics and kinetics of pharmaceutical systems from molecular simulation *J. Anwar*, Bradford, United Kingdom	Risk analysis and evaluation of scientific evidence for nutraceuticals in Japan *H. Ohama*, Tokyo, Japan
09:05	Pathophysiological concepts as a basis for the measurement of treatment response in inflammatory and obstructive airway disease *H. Reddel*, Camperdown, Australia	Computer aided design and optimisation for pharmaceutical formulations *K. Takayama*, Tokyo, Japan	Risk assessment and benefit evaluation for neutraceuticals *J. Hathcock*, Washington, DC USA
09:40	**Coffee Break**		
10:10	PET imaging for evaluation of drug effects in neuropsychiatric disease *M. Laurelle*, Greenford, United Kingdom, and New York, NY USA	Cyberinfrastructure enabled pharmaceutical products design and engeneering opportunities and challenges *V. Venkatasubramanian*, West Lafayette, IN USA	Benefits of antioxidants *H.K. Biesalski*, Hohenheim, Germany
10:45	Sensitivity of the items of the Montgomery Asberg depression rating scale to treatment response: Impact of different endpoints on clinical study design for antidepressant drugs *G. Santen*, Leiden, The Netherlands (TU-S04-1)	Expert system software for solid dosage form formulation design. *E. Krausbauer*, Basel, Switzerland (TU-S05-1)	Organic vs. conventional apple juices: polyphenol profile, anti-oxidant capacity, anti-cancer activity, and inflammatory bowel disease modulator activity *E. Mejia-Meza*, Pullman, USA (TU-S06-1)
11:00	Application of computation in translational research: A randomized trial of intravesical mitomycin c for superficial bladder cancer with 10-year follow-up *J. Au*, Columbus, OH USA (TU-S04-2)	Fundamental understanding through simulations? *S.-M. Siiriä*, Helsinki, Finland (TU-S05-2)	Effects of essential fatty acids on expression level and function of P-glycoprotein in inflammatory bowel diseases *A. Nomura*, Tokyo, Japan (TU-S06-2)
11:15	**Posters** **Lunch Break**		
	Parallel Symposium **Room: Auditorium** Have omics technologies improved the chance for successful drug development?	**Parallel Symposium** **Room: L** Are pharmaceutical manufacturing technologies in stagnation?	**Parallel Symposium** **Room: C-D** Are we using the right outcome measures to ascertain patient benefit from drug therapy?
	Co-chairs *T. Guentert*, Basel, Switzerland *M. Bleavins*, Ann Arbor, MI USA	Co-chairs *J. Fix*, Lawrence, KS USA *Y. Capan*, Ankara, Turkey	Co-chairs *G. Skrepnek*, Tucson, TX USA *A. Hussain*, Dubai, United Arab Emirates
14:15	Genomics and drug discovery: Have the promises been fulfilled? *K. Lindpaintner*, Basel, Switzerland	The changing landscape of pharmaceutical manufacturing: Incremental or breaking new ground? *J. Fix*, Lawrence, KS USA	Outcomes measurement: Overview of theoretical and applied issues *G. Skrepnek*, Tucson, TX USA
14:50	Omics and the search for improved biomarkers *M. Bleavins*, Ann Arbor, MI USA	Innovation needed in pharmaceutical research and technology in the 21st century *R. Ibuki*, Yaizu, Japan	Outcome measurement: Issues and strategies for pre-market development *W-F Huang*, Taipei, China Taiwan
15:25	Changing the drug development paradigm: Opportunities offered by new technologies *J. Kuromitsu*, Tsukuba, Japan	Can new production technologies and new excipients meet the demands of future drugs? *H. Frijlink*, Groningen, The Netherlands	Outcomes measurement: Issues and strategies for post-marketing development *J. Cooke*, Manchester, United Kingdom
16:00	Microarray analysis of chlamydia pneumoniae infected human epithelial cell line using gene ontology hierarchy *J. Alvesalo*, Helsinki, Finland (TU-S10-1)	Monitoring the modification of budesonide-lactose interactions within dry powder inhaler formulations using atomic force microscopy *F. Buttini*, Parma, Italy (TU-S11-1)	Abuse & misuse of lifestyle drugs in Korea *K. Kwon*, Seoul, South-Korea (TU-S12-1)
16:15	Quantitative proteomic analysis of human renal cell carcinoma using the NBS method J. *Matsumoto*, Kobe, Japan (TU-S10-2)	Production of beclomethasone and salbutamol loaded poly(lactic acid) nanoparticles by a novel electrospraying technique *L. Peltonen*, Heksinki, Finland (TU-S11-2)	Combined prescriptions of cardiovascular drugs and Ginkgo biloba in Taiwan: A population-based study *L.-C. Chang*, Tapei, China Taiwan (TU-S12-2)
16:45-18:15	**EUFEPS Afternoon Sessions** *See pages 18-20*		

SCIENTIFIC PROGR

	Parallel Symposium **Room: N-O** How to manage drug therapy at the extremes of age?	**Parallel Symposium** **Room: Forum** How can nanotechnology and materials science solve drug delivery problems?	**Parallel Symposium** **Room: Auditorium** How important is genetic and physiological variability in drug transporters?
	Co-chairs *H. Derendorf,* Gainesville, FL USA *H. Christensen*, Oslo, Norway	Co-chairs *C-M. Lehr*, Saarbrucken, Germany *H. Ghandehari*, Baltimore, USA	Co-chairs *K. Giacomini,* San Francisco, CA USA *K . Inui,* Kyoto, Japan
08:30	Pharmacotherapy in the elderly *H. Derendorf*, Gainesville, FL USA	Nanomedicines for overcoming biological barriers *C-M. Lehr*, Saarbrucken, Germany	Functional genomics of membrane transporters *K. Giacomini*, San Francisco, CA USA
09:05	Pharmacokinetics and pharmacodynamics in neonates and infants *T. Dalla Costa*, Porto Alegre, Brazil	Particle design for absorption enhancement using a 4-nozzle spray drier and DNA vaccine by self-organised Tat nanospheres *H. Okada*, Tokyo, Japan	Pharmacogenomics of MDR1/ABCB1 and CYP3As in tacrolimus therapy after organ transplantation *K . Inui,* Kyoto, Japan
09:40	**Coffee Break**		
10:10	Dose optimisation in neonates, infants and children *S. Higuchi*, Fukuoka, Japan	Can higher definition of the nanoscale result in better drug delivery systems in the 21st century? *H. Ghandehari*, Baltimore, USA	Assessing the impact of variability in ABC drug transporters using mouse models *A. Schinkel*, Amsterdam, The Netherlands
10:45	Prediction of the oral bioavailability of midazolam in the first 2 years of life *T. N. Johnson,* Sheffield, United Kingdom (WE-S01-1)	Development of octaarginine-modified multifunctional envelope-type nano device for gene delivery *K. Kogure,* Sapporo, Japan (WE-S02-1)	Web-based comprehensive database for all about drug transporters, "TP-Search" *K. Maeda,* Tokyo, Japan (WE-S03-1)
11:00	Towards the in silico child: midazolam pharmacokinetics using physiologically-based pharmacokinetic vs. non-linear mixed effects modeling *S. Willmann,* Leverkusen, Germany (WE-S01-2)	*In vitro* studies into the biological fate of pva nanoparticles for pulmonary delivery *M. Orlu,* Istanbul, Turkey (WE-S02-2)	Regulatory mechanisms for gene expression of human organic anion transporters *K. Ogasawara,* Kyoto, Japan (WE-S03-2)
11:15	**Posters** **Lunch Break**		
	Keynote Presentation **Room: Auditorium** Sponsoring Organisation AstraZeneca life inspiring ideas	**Keynote Presentation** **Room: Forum**	
	Chair *J. Pritchard,* Macclesfield, United Kingdom	Chair *K. Midha*, Saskatoon, Canada	
12:15	Drug resistance in cancer chemotherapy *T. Tsuruo*, Tokyo, Japan (KLW-1)	Recent progress in prion biology *M. Heikenwaelder*, Zurich, Switzerland (KLW-2)	
	Round Table Discussion **Room: A**	**Round Table Discussion** **Room: A**	**Round Table Discussion** **Room: C-D**
13:10	What is the value of observational data post-marketing to assess safety and efficacy? Convenor *M. Rowland*, Manchester, United Kingdom	Life-style drugs: a new burden to the health system? Convenor *G. Alvan*, Uppsala, Sweden	Is there a consensus on guidelines for the evaluation of biosimilars? Convenor *V. Shah*, Rockville, MD USA
	Parallel Symposium **Room: N-O** Is the patient taking the tablets?	**Parallel Symposium** **Room: Auditorium** Developing biotech products: What are the challenges and solutions? Sponsoring Organisation AstraZeneca life inspiring ideas	**Parallel Symposium** **Room: Forum** Control of intracellular pharmacokinetics: Advantages for drug therapy?
	Co-chairs *M. Roberts*, Brisbane, Australia *J. Kennedy*, Cork, Ireland	Co-chairs *M. Tsuchiya*, Gotenba, Japan *S. Frokjaer,* Copenhagen, Denmark	Co-chairs *H. Kroemer*, Greifswald, Germany *D. Roden*, Memphis, TN USA
14:15	When are dose administration aids of benefit? *M. Roberts*, Brisbane, Australia	The challenge of the next generation of therapeutic antibodies *M. Tsuchiya*, Gotenba, Japan	Transporter mediated cellular uptake of drugs as a prerequisite for drug action *H. Kroemer*, Greifswald, Germany
14:50	Ambulatory patient's variable adherence with prescribed drug dosing regimens: Prevalence, patterns, practicalities for drug trials and patient care *J. Urquhart*, Palo Alto, CA USA, and Maastricht, The Netherlands	Drug delivery systems for biopharmaceuticals *S. Frokjaer*, Copenhagen, Denmark	Intracellular pharmacokinetics determines drug action in patients with HIV *R. Kim*, London, Canada
15:25	Medication errors and human factors in medication use safety *P. Schneider,* Columbus, OH USA	Efficient transepithelial delivery of biopharmaceuticals *J. Mrsny,* Cardiff, United Kingdom, and Menlo Park, CA USA	Understanding drug-induced arrhythmias – from intracellular concentrations to candidate genes *D. Roden*, Nashville, TN USA
16:00	Routine use of dose administration aids (DAAs) in the community - characteristics of Australian consumers making this choice *J. Stokes*, Brisbane, Australia (WE-S07-1)	Oral delivery of insulin by new polysaccharide nanoparticles *B. Sarmento,* Porto, Portugal (WE-S08-1)	Methods in drug discovery: measurement of unbound intracellular drug concentrations *M. Friden,* Uppsala, Sweden (WE-S09-1)
16:15	A cross-national study of persistence of antihypertensive medication use in the elderly *B. L. Van Wijk,* Utrecht, The Netherlands (WE-S07-2)	High pressure treatment for the recovery of active protein from protein aggregates: An enabling technology in comparison to traditional chaotrope-based refolding methods *M. Seefeldt,* Boulder, USA (WE-S08-2)	Uptake mechanisms of anti-hiv drugs, 2', 3'-dideoxyinosine and 3'-azido-3'-deoxythimidine by a conditionally immortalized syncytiotrophoblast cell line, TR-TBT *K. Sato,* Tokyo, Japan (WE-S09-2)

AMME • Wednesday

	Parallel Symposium **Room: A** Systems biology: A driver of drug discovery and development? Sponsoring Organisation 	**Parallel Symposium** **Room: C-D** How to engineer desired particle properties for drug delivery?	**Parallel Symposium** **Room: L** Off-label use of medicines: Abuse or a vehicle for innovation?
	Co-chairs *C.R. Noe,* Vienna, Austria	Co-chairs *E. Fattal*, Paris, France *T. Nagai*, Tokyo, Japan	Co-chairs *A. Kalis*, The Hague, The Netherlands
08:30	Systems Biology: What does it mean for pharmaceutical sciences? *A. Aszódi,* Vienna, Austria	Particle design for nucleic acids and contrast agents *E. Fattal*, Châtenay-Malabry, France	Two worlds and why the twain will never meet *J. Lisman*, Amstedam, The Netherlands
09:05	The theory of biological robustness and its applications to medicine *H. Kitano*, Tokyo, Japan	Novel particle design for drug delivery *H. Takeuchi*, Gifu, Japan	Regulatory and ecomonic aspects of off-label drug use *A. Wertheimer,* Philadelphia, PA USA
09:40	**Coffee Break**		
10:10	Reconstruction of the genome-wide human metabolic networks: conceptual and practical uses *B. Palsson*, La Jolla, CA USA	How to optimize particle properties for pulmonary drug delivery *G. Hochhaus*, Gainesville, FL USA	The benefits of off-label grug use and its utilisation *K. Tsutani*, Tokyo, Japan
10:45	From enzymes to cells and back: Integrating biochemical and cellular profiling of small molecule kinase inhibitors *J. J. Hornberg,* Oss, The Netherlands (WE-S04-1)	The role of particle characterization in the development and dosage form evaluation of a poorly soluble pharmaceutical drug product *R. Govoreanu,* Beerse, Belgium (WE-S05-1)	On-label and off-label prescribing of erythropoietic agents (epoetin alfa and darbepoetin alfa) in critically ill patients: a multi-center, retrospective study *D. Holdford,* Richmond, USA (WE-S06-1)
11:00	Pharmbiosim - biosimulation of drug metabolism *J. Smolinski,* Dresden, Germany (WE-S04-2)	Supercritical fluid particle design for increasing dissolution rate of poorly-soluble active pharmaceutical ingredients *F. Deschamps,* Champigneulles, France (WE-S05-2)	High rate of off-label use in cardiovascular paediatric pharmacotherapy requires new focus in research *L. Hsien*, Düsseldorf, Germany (WE-S06-2)
11:15	**Posters** **Lunch Break**		
	Parallel Symposium **Room: A** Molecular targeting in cancer chemotherapy?	**Parallel Symposium** **Room: C-D** Miniaturisation in analytical methods: Is small always beautiful?	**Parallel Symposium** **Room: L** Counterfeiting of medicines: Detection and prevention?
	Co-chairs *J. Au*, Columbus, OH USA *S. Eck*, Ann Arbor, MI USA	Co-chairs *S. Lunte*, Lawrence, KS USA *J. Haginaka*, Nishinomiya, Japan	Co-chairs *A. Moffat*, London, United Kingdom *Z. Y. Yang*, Guangzhou, China
14:15	The challenges of developing targeted cancer therapies: An industry perspective *S. Eck*, Ann Arbor, MI USA	Separation based sensors for pharmaceutical analysis using microdialysis and microchip electrophoresis *S. Lunte*, Lawrence, KS USA	New methods for detection of counterfeit medicines for laboratory and field use *A. Moffat*, London, United Kingdom
14:50	A systems pharmacology: Targeting p53 networks *E. Liu*, Singapore, Singapore	Micro and nano chemical systems on chips for analytical and biological sciences *T. Kitamori*, Tokyo, Japan	Analytical methods to detct and fingerprint counterfeit medicines *F. Fricke,* Cincinnati, USA
15:25	Translational research on a drug with multiple molecular targets (suramin) *J. Au*, Columbus, OH USA	Microchip array strategies for biomarker detection using fluorescence and MALDI TOF MS readout *T. Laurell*, Lund, Sweden	Combating counterfeit drugs in Asia *Z. Y. Yang*, Guangzhou, China
16:00	Anti-angiogenic actions of liposomal glucocorticoids on tumor growth *M. Banciu,* Utrecht, The Netherlands (WE-S10-1)	Molecular imaging of redox reaction using OMRI/nitroxyl probe technique *K.-I. Yamada,* Fukuoka, Japan (WE-S11-1)	Transfer of an NIR method for the authentication of tablets and the detection of counterfeit versions *A. J. O'Neil,* London, United Kingdom (WE-S12-1)
16:15	Characterization of paclitaxel-loaded immunonanoparticles *A. Cirstoiu-Hapca,* Geneva, Switzerland (WE-S10-2)		Spurious drugs –epidemic threat to public health and pharma industries *V. Mshra,* Sagar, India (WE-S12-2)

Monday

EUFEPS Afternoon Sessions

	Room: O	Room: L	Room: N-O
	Strategic, innovative and critical drug research initiatives: One year late Chair *O.J. Bjerrum*, Copenhagen DK	Pharmaceutical sciences research training and education: Needs and supply Chair *M. Van der Waart*, Oss NL	The EU Microdosing AMS Partnership Programme (EUMAPP) Chair *R.A. de Zeeuw*, Assen NL
16:45-18:15	Strategic drug research initiatives in Europe: Current and future needs *O.J. Bjerrum*, Copenhagen DK The European Innovative Medicines Technology Platform: Current status 2007 *B. Rainer*, Brusels BE Precompetitive industry collaboration in Europe: 18 months experience of the InnoMed project on predictive toxicology *D. Tweats*, Swansea UK Precompetitive industry collaboration in Europe: 18 months experience of the InnoMed project on biomarkers for Alzheimer's disease *P. Francis*, London UK Discussion	University perspective *S. de Smedt*, Ghent BE Industry perspective *J. Dirach*, Copenhagen DK PPP Reserach Perspective *V. Nickolson*, Leiden NL Discussion	Microdosing: Pros and cons in translational medicine *C. Garner*, York UK EUMAPP: Objectives, approaches and current status *B. Oosterhuis*, Zuidlaren NL Microdosing: Servier strategy and expectations from EUMAPP *E. Foos-Gilbert*, Courbevoie FR Discussion

Tuesday

EUFEPS Afternoon Sessions

	Room: E	Room: L	Room: C-D
	European drug development centres and European growth areas Chair *P. Vuorela*, Turku FI	Reformulation of old drugs: Life cycle management Chair *H. Blume*, Oberursel DE	Vaccine delivery Co-Chairs *J. Bouwstra*, Leiden NL *W. Jiskoot*, Leiden NL
16:45-18:15	Center for New Drug Discovery Tools - DDTC *A. Urtti*, Helsinki FI The Pharma game, new rules, new players *V. Nickolson*, Leiden NL Drug development in the Medicon Valley: Importance of the binational cluster and its international contacts *S. Gestrelius*, Copenhagen DK Discussion	Modified drug delivery – development rationale for therapeutic improvement *E. Soederlind*, Moelndal SE Product preformance in the gastrointestinal tract and perspectives for optimisation *W. Weitschies*, Greifswald DE Life Cycle Management: new chances for for old drugs *H. Blume*, Oberursel DE Discussion Session Sponsor SoeraTec R&D	Virosomes as a platform for improved influenza vaccines *A. Huckriede*, Groningen NL Vaccines for Hepatitis B using DNA and subunit antigens *Y. Perrie*, Aston UK Challenges in non-invasive vaccine delivery *W. Jiskoot*, Leiden NL Discussion

Strategic, Innovative and Critical Drug Research Initiatives: One Year Later

Large initiatives to promote drug sciences, supporting the European pharma industry, have recently been launched or are in their late phase of preparation. Major ones include the European 7th Framework Programme for Research and Technological Development, as well as the Innovative Medicines Initiative (IMI) by the European Pharmaceutical Industries and Associations (EFPIA) and the European Commission, including the InnoMed, PredTox and AddNeuromed projects. Substantial experience of working together in new constellations is gained, already, and considered producing a role model for future collaboration in new IMI projects.

Current status of these initiatives and experiences obtained to date will be presented. Presentations will also be an introduction to a discussion about best practice for joint projects and initiatives.

Pharmaceutical Sciences Research Training and Education: Needs and Supply

Traditionally, academia is primarily involved in defining and executing training and education programmes, as lectures, workshops and courses. The EUFEPS Committee on Training and Education (CTE; www.eufeps.org) is also involved in defining and organising training activities, which will be introduced and discussed.

Education and training is an important activity of the Innovative Medicines Initiative (IMI; www.imi-europe.org). The IMI is a public-private partnership, including patient organisations, universities, hospitals, and regulatory authorities as well as small and large biopharmaceutical and healthcare companies. Drug efficacy, safety, knowledge management and education and training are all pillars of the IMI.

The newly established Dutch Top Institute Pharma (see other summary) puts strong emphasis on training and education. It is a practical example how three partners, all needing well educated and trained scientists are working closely together.

The EU Microdosing AMS Partnership Programme (EUMAPP)

Microdosing is a new safe way to obtain essential human drug metabolism and pharmacokinetic (PK) information with minimal animal testing. Both the European and the US regulatory authorities have published microdosing guidance documents and are open for business. The scientific basis of microdosing relies on that there is reasonable predictivity between microdose and pharmacological dose PK.

noon Sessions

Monday

EUFEPS Afternoon Sessions

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	Room: E	Room: C-D
	The European Pharma Sciences Leadership Forum (EuPSLF) Chair *C.R. Noe*, Vienna AT	Pharmaceutical sciences *in silico* learning systems: Value and availability Chair *N. Haider*, Vienna AT
16:45-18:15	Background, initiative and progress *H. H. Linden*, Stockholm SE Aims, ambitions and plans *R. Pellicciari*, Perugia IT Preparing for a changing world of science *C.R. Noe*, Vienna AT Discussion	Computer applications in pharmaceutical education and research *B. Ernst*, Basel CH Pharmasquare – Blended Learning in Pharmaceutical Sciences S. *Moss*, Bath UK PharmXplorer, an integrated platform for e-learning in pharmaceutical sciences *T. Langer*, Innsbruck AT Discussion Session Sponsor

Tuesday

EUFEPS Afternoon Sessions

	Room: O	Room: A	Room: N-O
	Pharmacogenetics & Pharmacogenomics Workshop: Outcomes and plans Chair *A-H. Maitland-van der Zee*, Utrecht NL	How to start up a new company? Co-Chairs *H. Lennernäs*, Uppsala SE *C. Bogentoft*, Stockholm SE	Drug product quality after new legislation Chair *H. Köszegi-Szalai*, Budapest HU
16:45-18:15	Pharmacocgenetics of adverse drug reactions *M. Pirmohamed*, Liverpool UK Pharmacocgenetics in peadiatrics *E. Jacqz-Aigran*, Paris FR Methods in pharmacogenetics/genomics *A-H. Maitland-van der Zee*, Utrecht NL Discussion	Bridging between entrepreneurs and the pharmaceutical industry *H. Lennernäs*, Uppsala SE The hands-on experience *G.T. Tucker*, Sheffield UK The Karolinska Innovation model in starting up companies *C. Bogentoft*, Stockholm SE Discussion	The impact of new guidance documents on the quality of medicines in Europe *D. van Riet*, Bilthoven NL The present and the expectable future role of the EP in the standardisation of the quality of medicines in Europe *H. Köszegi-Szalai*, Budapest HU Discussion

EUMAPP is a grouping of 10 companies and organisations funded by the EU to a value of over 3 million euros who are undertaking an ambitious programme to (1) examine microdose/pharmacological dose comparisons for seven drugs (2) use microdose PK data to better model human PK in combination with *in silico* and *in vitro* methods (3) compare different analytical approaches and (4) to disseminate the results to both professional and lay people. Will EUMAPP help to put microdosing into the critical path of drug development?

The European Pharma Sciences Leadership Forum (EuPSLF)

The process of drug discovery, development and utilisation for the improvement of human and animal health and welfare is a complex process that involves many individual scientists and organisations from a wide variety of scientific backgrounds. They form scientific communities that, directly and indirectly, contribute to better, new, innovative and safe medicines.

Initiatives towards a "European Pharma Sciences Leadership Forum", comprising the presidents of ten partnering federations and associations, were taken less than one year ago. It is under way and should work for advancing science, engage in European strategic research initiatives, and contribute to relevant training and education of scientists in the wide field of pharmaceutical and related research and development. Speaking up with one voice would, furthermore, demonstrate united commitment to solving problems and setting priorities for both short- and long-range new drug developments and applications in Europe.

Pharmaceutical Sciences *In-silico* Learning Systems: Value and Availability

Academic education in the pharmaceutical sciences is facing a rapidly increasing amount of available information (new insights, latest research results, emerging new disciplines), which has to be turned into profound knowledge, excellent theoretical and practical skills, and decision-making capabilities of our students and graduates. State-of-the-art information technology is becoming increasingly important in making teaching/learning processes more efficient. This technology has the potential to strengthen the classical link between scientific research and education.

Today, "*in-silico* learning", "computer-aided learning", "eLearning", or "blended learning" is going to grow from scattered pilot projects, initiated by a few pioneers, into larger

initiatives on a regional, national, and increasingly international level, especially in the pharmaceutical sciences. Such larger "*in-silico* learning" initiatives will be our focus, including "live" demonstrations.

European drug development centres and European growth areas

The Drug Discovery and Development Technology Centre is a new research centre located in the Faculty of Pharmacy, University of Helsinki. It is a multi-disciplinary unit concentrating on improved technologies for preclinical drug discovery and development.

The Duch Top Institute Pharma is a public-private partnership, including universities, academic medical centres, small, medium and large life science companies. Academic and industrial parties contribute know-how as well as other resources. It is their goal to develop novel, cross-disciplinary drug discovery and development processes that will reduce "time and cost to patient".

The Medicon Valley Academy is a network of universities, hospitals and companies. The cluster itself, and the drug development activities of it are, primarily, in the "Medicon Valley" (Copenhagen DK and in Malmö/Lund SE region). Goals include improving Danish-Swedish collaboration. Collaboration with ScanBalt links to other Nordic/Baltic Sea initiatives and organisations.

Reformulation of Old Drugs: Life Cycle Management

Could the life cycle of drugs available since long be further expanded? Utilising and combining the wealth of knowledge and experience gained of old drugs with new scientific insights and regulatory requirements should provide such an opportunity for improved drug therapy. Approaches in doing this include, for example, improved and modified drug delivery at the target of drug action. For oral drugs, product performance in the gastrointestinal tract and how to optimise it is crucial. Perhaps, not all old drugs would survive, but for many systematic "Life Cycle Management" will provide new chances.

In this session, the above and related issues will be addresses by experts and further discussed.

Vaccine Delivery

The proper delivery of antigens is a major hurdle in the search for potent vaccines against several priority diseases, such as tuberculosis, HIV/AIDS, malaria, and pandemic influenza. The choice for a certain delivery vehicle depends on the physicochemical characteristics of the antigen(s), the disease and type of immune response that is desired (e.g., Th1/Th2 ratio), as well as the route of administration.

In this session several hot topics in vaccine delivery will be presented and discussed, including innovative delivery systems for (pandemic) flu and hepatitis B vaccines, delivery issues in the field of genetic (DNA) vaccination, and needle-free vaccine delivery approaches.

Pharmacogenetics & Pharmacogenomics Workshop: Outcomes and Plans

A workshop was set up, recently, to bring European scientists in pharmacogenetics and pharmacogenomics together to start developing a roadmap for better collaboration and intensified research, including a network among them and their groups, also towards personalised medicines. Development recommendations from the workshop included, for example: Platform for gathering and promoting knowledge about pharmacogenetics in Europe; mechanisms for sharing and extending existing research, databases and bio-banks; extended collaboration between academia and the pharmaceutical industry; better education and training in pharmacogenetics and genomics; and increased European funding.

Presentations of this session will focus on important research areas and tools, all to further encourage and stimulate discussion, new initiatives and collaborations. Input in the discussion on how to proceed as to the network will be welcome.

How to Start up a New Company?

The first contribution of this session will present a network that supports developments and investments in life science. It links 20 partners with extensive industrial, scientific and entrepreneurial experience, covering the whole value chain, from chemical, pharmaceutical and clinical development to management, intellectual property IP, financing, and commercial exit of projects.

The second one will contribute hands-on experience of a research-based drug development and information management consultancy, delivering leading-edge science that accelerates drug discovery and development. Development of algorithms, databases and software that incorporate physiological, genetic and epidemiological information are in the main focus.

Promoting results of biomedical research to develop new products and applications are the focus of the third presentation. It supports researchers in developing their research results commercially, providing such as project management, funding for patent protection, legal advice and business development, etc.

Drug Product Quality: Needs and Performance

An overview will be provided of recent changes in the pharmaceutical legislation („euroreference preparation" concept, tightening timeframes etc.) and of the new guidance documents issued by the ICH and/or the EMEA, which have an impact on the requirements for the content of quality documentation and on the principles and practice of quality assessment. The well detectable shift from analysing the end products to the more thorough understanding, design and control of the API and product manufacture and application of the concept in the daily routine of dossier compilation and assessment are major current issues of the standardisation of quality of medicines.

After this, we will summarise the legal status of EP monographs and general chapters in the current European pharmaceutical regulatory environment. Applicability and limitations of common standards for articles produced by different manufacturers, via different manufacturing techniques, will be illustrated by several examples in the presentation. Advantages and potental risks of inclusion of guidance documents in the pharmacopoea will also be discussed by the speaker.

Career Centre: Are You Looking for New Career Opportunities?

During the Pharmaceutical Sciences World Congress, FIP is organising a Career Centre. So if you are looking for a new job, want to take your current career in a different direction, or just want to get into contact with representatives from leading pharmaceutical companies, we invite you to participate in this unique event.

Whatever changes or developments you are looking to make within your career, the FIP Career Centre during the PSWC will have something to offer you!

The goal of the Career Centre is to bring Ph.D. students, post doctoral fellows and those individuals already embarked on their career path into contact with representatives from leading pharmaceutical industries and other potential employers. During the FIP Career Centre, opportunities will be available to speak to these representatives, both for informal discussions Centreed around job opportunities, or for a pre-arranged interview for one of the positions posted on the FIP Career Centre website. New job opportunities can and will also be posted throughout the Congress.

The Career Centre will be ongoing throughout the days of the PSWC and will welcome candidates to speak with industry delegates privately in designated recruitment rooms at the Career Centre. Also company presentations will be held. For specific programme details please look on www.fip.org/careerCenter or on the message board in the Forum Area.

Thanks are extended to the Founding Partners of this initiative, AstraZeneca and Pfizer.

For more information and free participation by uploading your CV, please visit:
www.fip.org/careerCenter

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FIP Career Centre at PSWC2007

What?

A Career Centre where participants are able to have informal discussions with company delegates or be invited for one of the pre-arranged job interviews.

Who?

The Career Centre is for Ph.D. students, post doctoral fellows but also for individuals working in the pharmaceutical industry.

How do I participate?

Step 1: Upload your CV on the FIP Career Centre website: www.fip.org/careercenter
Step 2: Apply for one of the jobs posted or wait for an invitation for a general interview after posting your CV
Step 3: Be invited by e-mail for a job interview or a more informal discussion in one of the private recruitment rooms

When?

April 22 - 25 during the PSWC 2007, every day from 09:00 - 18:00 hours.

Where?

Amsterdam RAI, at the Career Centre, Rooms F and G on the first floor (Auditorium Area).

More information

Additional information during the congress can be found on the Message Board (Forum Area) or on the website www.fip.org/careercenter

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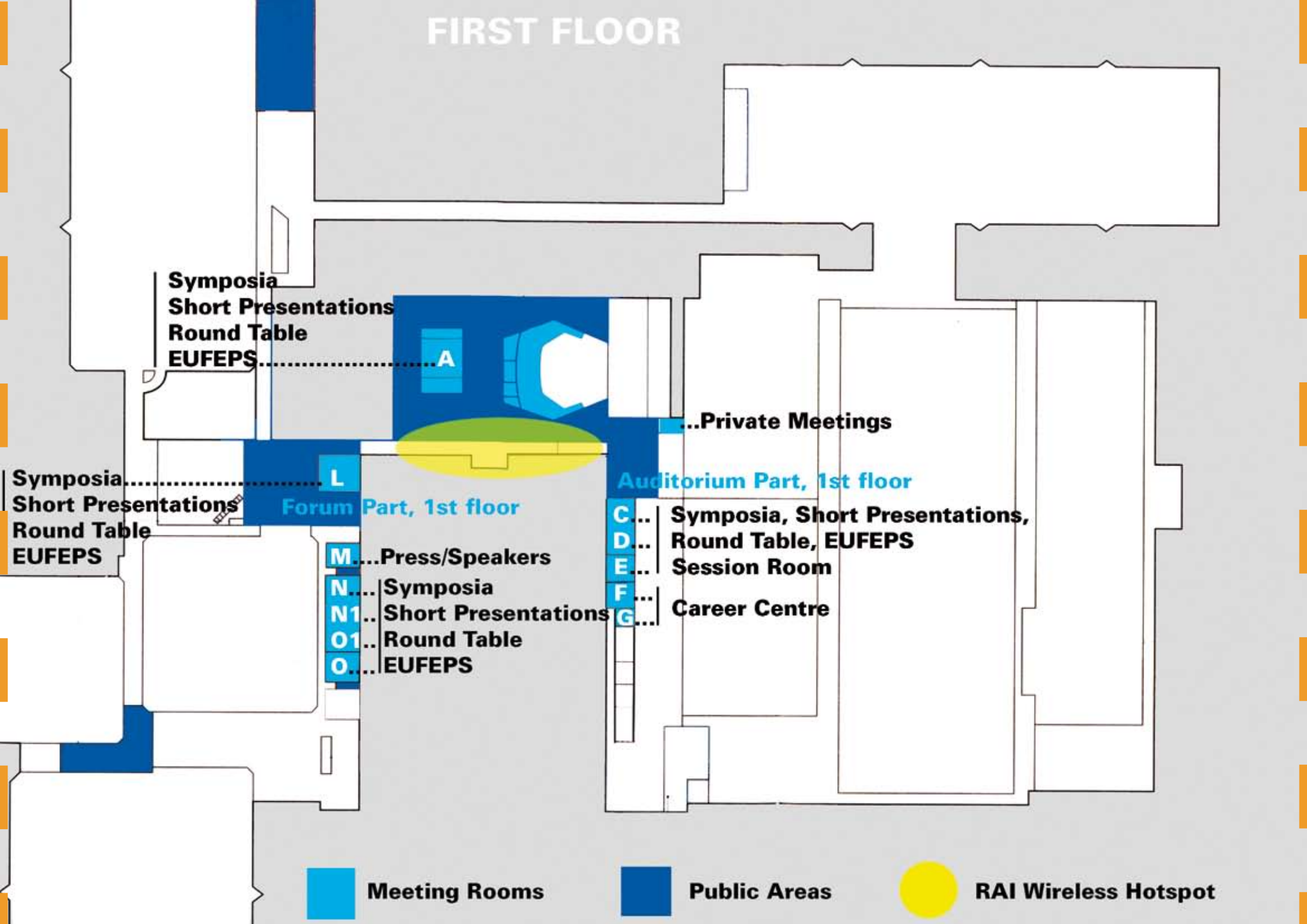
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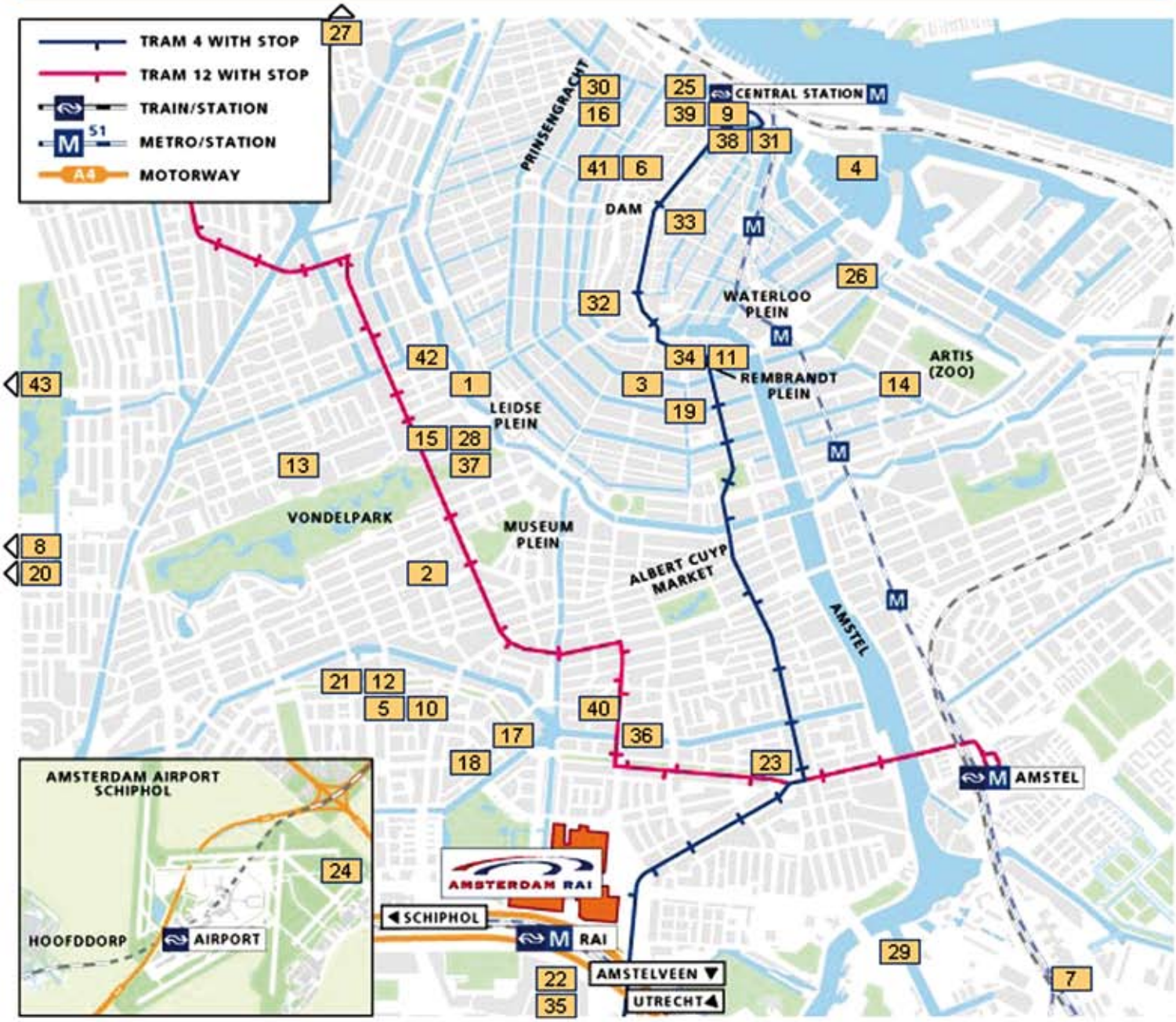
Posters
Food Station
Congress Office
GROUND FLOOR

Map of Amsterdam



1 ACH Leidse Square Hotel
2 ACH Trianon Hotel Amsterdam
3 Albus Grand Hotel
4 Amstel Botel
5 Apollofirst - A Hampshire Classic Hotel
6 Avenue Hotel
7 Bastion Hotel Amsterdam / Amstel
8 Bastion Hotel Amsterdam / Centrum-ZW
9 Bellevue
10 Best Western Delphi Hotel
11 Best Western Eden Hotel
12 Bilderberg Garden Hotel
13 De Filosoof
14 Eden Lancaster Hotel
15 Europa 92 Hotel
16 Golden Tulip Amsterdam Centre
17 Golden Tulip Apollo Amsterdam
18 Hampshire Hotel Beethoven
19 Hampshire Inn - Prinsengracht
20 HEM Hotel Amsterdam
21 Hilton Amsterdam
22 Holiday Inn Amsterdam
23 Hotel V
24 Ibis Amsterdam Airport
25 Ibis Amsterdam Centre hotel - restaurant
26 Ibis Amsterdam City Stopera
27 Ibis Amsterdam Westcorner
28 Marriott Amsterdam
29 Mercure aan de Amstel
30 New Amsterdam
31 NH Barbizon Palace
32 NH City Centre
33 NH Grand Hotel Krasnapolsky
34 NH Schiller
35 Novotel Amsterdam
36 Okura Amsterdam
37 Owl Hotel
38 Park Plaza Victoria Hotel Amsterdam
39 Ramada Amsterdam City Centre
40 Savoy Hotel Amsterdam
41 Sofitel Amsterdam
42 Tulip Inn Amsterdam Centre
43 Tulip Inn Amsterdam City West

The **GVB 72 hours ticket** is by far the easiest way of travelling. The ticket only needs to be stamped once, at the beginning of your first journey. After stamping, you can make unlimited use of GVB trams, buses, metro and night buses for a period of 72 hours (3 days).

General Information

Badges

All delegates and accompanying persons will receive a personal badge upon registration in the Forum Foyer of the RAI Exhibition and Congress Center as of Sunday 22 April, 2007. All participants and accompanying persons are kindly requested to wear their badges throughout the congress. Only participants wearing their name badge will be admitted to the sessions, exhibition in Hall 10, Opening Session and Welcome Reception. Accompanying persons wearing their name badge are welcome to the Exhibition Hall 10, Opening Session and Welcome Reception.

Business Hours

Banks are open from 09:00-16:00 from Monday to Friday. Shops and Department Stores are generally open from 10:00-18:00.

Congress Reception and Dinner

A Welcome Reception will take place on Sunday, April 22, 2007, after the Opening Ceremony in Hall 10 of the RAI Convention Center.

The Congress Dinner is planned on Tuesday, April 24, 2007 in the famous Wintergarden of the Grand Hotel Krasnapolsky, in the city centre. The event is optional and if there are still tickets available, you can purchase them at the on-site registration desk in the Forum Foyer.

Credit cards

Hotels, Shops and Restaurants usually accept all credit cards.

Climate

The congress will take place in April. Temperatures are between 15-20 degrees Celsius.

Currency

The currency used in The Netherlands is EURO.

VAT

VAT (value added tax) in the Netherlands is on most items 19%.

Electrical Appliances

Electrical appliances in The Netherlands operate on 220 volts.

Food Stations

From 11:15 until 14:00 hours there will be food stations in Hall 10.

Housing Agent

RAI Hotel Services has a booth in the registration area of the Forum Foyer.

Insurance

The Organising Committee accepts no liability for personal injuries sustained, sickness or for loss or damage to property belonging to congress participants and/or accompanying persons, incurred either during or as a result of the congress. It is recommended that each participant takes out a personal insurance.

Internet Hot Spots

There are several Hot Spots in the Lobby of the Auditorium. There are computers, tables and chairs. Prices: Euro 7.50 for 1 hour - Euro 19.00 for 24 hours (can be used over various days and time slots). Credit card payment is Euro 0.20 per minute (minimum of 15 minutes).

Language

The official congress language is English. No simultaneous interpretation will be provided.

Public Transport

Train: Amsterdam RAI is easily accessible by train. Air travelers can make use of a direct train connection (4 times per hour). From the RAI station it is a 5 minutes walk to the RAI venue. Trains from/to Roosendaal/Belgium/France call at Schiphol. There are direct connections from Rotterdam, The Hague and Leiden. From Amsterdam Central Station you can take the Amstelveen express tram 51 (travelling time is 12 min.; exit at the RAI station) or tram 4 (travelling time is 30 min.; exit at RAI Europaplein).

Presentation Equipment and Speakers Preview Room

All Session rooms are equipped with a laptop and LCD projection. All speakers are requested to proceed to the Speakers/Press Room: Room M 1st floor of the Forum

Part to check their presentation. A copy of each presentation will be asked by the technician for use in the Press Room and as general back up. Speakers are requested to hand over their memory stick to the technician in each session room, 30 min prior to the morning and afternoon sessions and collect it from the technician at the end of the session.

In your Registration envelope you will find a form on which speakers will be asked whether their (modified) presentations will be available for electronic dissemination upon request as a pdf file.

Press Room

All press representatives are requested to register in the Pre-registration area of the Forum Foyer after which they should proceed to Room M 1st floor Forum Part.

Tipping

It is not necessary to give tips in taxis or restaurants. Service is included in the bill.

However if you are very satisfied with the performance you could round up the bill.

Accreditation by KNMP & NVFG

The Royal Dutch Pharmaceutical Society KNMP has accredited PSWC2007 as a continuing education course for community pharmacists (NL) for 0.5 credit point per half day (accreditation number CvD/1829). Participants who wish to apply have to sign the presence list at the entrance of the session room. The Netherlands Association of Pharmaceutical Physicians NVFG has accredited it as well, with maximum 28 accreditation points (www.nvfg.nl).

Registration

The registration area is open from Sunday, April 22, 2007, until Wednesday, April 25, 2007, in the Forum Foyer of the RAI Convention Centre.

PSWC delegates registration fee includes:

- Access to all scientific sessions Access to the exhibition
- Final Congress Programme
- List of Participants
- Congress Bag
- Name Badge
- Invitation to the Opening Session, Sunday, April 22, 2007
- Invitation to the Welcome Reception, Sunday, April 22, 2007

On-site delegates will receive (if applicable)

- Proof of payment on PSWC letterhead
- Poster certificate on PSWC letterhead
- Certificate of attendance on PSWC letterhead

PSWC Accompanying persons registration fee includes:

- Access to the exhibition
- Name Badge
- Invitation to the Opening Session, Sunday, April 22, 2007
- Invitation to the Welcome Reception, Sunday, April 22, 2007

Payment

Registration fees are to be paid in Euro either in cash or by Credit card (Visa, Eurocard/Mastercard, American Express).

Student registration

- For on-site registration, please bring with you an official document signed by the Head of Department of your University proving your Ph.D Student/Recent Postdoc graduate status (three years after graduation).

Useful Addresses

PSWC2007 Congress Registration & Abstract Handling

NewBrooklyn
P.O. Box 73
NL-3620 AB Breukelen
The Netherlands
Tel +31 346 266110
Email
registration@newbrooklyn.nl

PSWC2007 Enquiries & Information

International Pharmaceutical Federation
FIP Congress & Conferences
Andries Bickerweg 5
P.O. Box 84200
NL-2508 AE The Hague
The Netherlands
Tel +31 70 3021982
Fax +31 70 3021998
Email pswc@fip.org
www.fip.org/PSWC

PSWC2007 Promotion & Website

Hans H. Linden
EUFEPS
P.O. Box 1136
SE-11181 Stockholm
Sweden
Tel +46 8 7235025
Fax + 46 8 4113217
Email hans.linden@eufeps.org
www.eufeps.org

PSWC2007 Accommodation & Reservation

RAI Hotel & Travel Service
P.O. Box 77777
NL-1070 MS Amsterdam
The Netherlands
Tel +31 20 5491927
Fax +31 20 5491946
Email hotelservice@rai.nl
www.rai.nl/hotelservice

PSWC2007 & PharmSciFair Exhibition

Chris Hanney
Health Links
3rd Floor, Windsor House
11A High Street
Kings Heath
Birmingham B14 7BB
United Kingdom
Tel +44 121 2483399
Fax +44 121 2483390
Email channey@health-links.co.uk
www.health-links.co.uk

Public Transport

5 STAR HOTELS	Distance to RAI	Tram to/from RAI - Bus to/from RAI
Bilderberg Garden - Mangerie de Kersentuin	5-10 min by Taxi	tram 5 (direc. Amstelveen Binnenhof) to station Zuid, change to metro 50 (direc. Gein) or metro 51 (direc. Central Station) to RAI
Hilton Amsterdam	5-10 min by Taxi	tram 5 (direc. Amstelveen Binnenhof) to station Zuid, change to metro 50 (direc. Gein) or metro 51 (direc. Central Station) to RAI
Marriott	City Center	tram 7 (direc. Flevopark) or tram 10 (direc. Azartplein) to Frederiksplein, change to tram 4 (direc. RAI) to RAI
NH Barbizon Palace	City Center	tram 4 (direc. RAI) to RAI
NH Grand Hotel Krasnapolsky	City Center	tram 4 (direc. RAI) to RAI
Okura	Walking distance	no tram
4 STAR HOTELS		
Apollofirst	5-10 min by Taxi	tram 5 (direc. Amstelveen Binnenhof) to station Zuid, change to metro 50 (direc. Gein) or metro 51 (direc. Central Station) to RAI
Best Western Delphi	5-10 min by Taxi	tram 5 (direc. Amstelveen Binnenhof) to station Zuid, change to metro 50 (direc. Gein) or metro 51 (direc. Central Station) to RAI
Golden Tulip Inntel Amsterdam Centre	City Center	tram 4 (direc. RAI) to RAI
Holiday Inn	Walking distance	
Le Meridien Apollo	5-10 min by Taxi	bus 15 (direc. Muiderpoort Station) to RAI
Mercure aan de Amstel	5-10 min by Taxi	metro 50 (direc. Isolatorweg) / metro 51 (direc. Amstelveen Westwijk) to RAI
NH Schiller	City Center	tram 4 (direc. RAI) to RAI
Novotel	Walking distance	walk
Savoy Hotel	Walking distance	bus 15 (direc. Muiderpport) to RAI
Victoria	City Center	tram 4 (direc. RAI) to RAI
Sofitel	City Center	tram 4 (direc. RAI) to RAI
3 STAR HOTELS		
Albus Grand	City Center	tram 4 (direc. RAI) to RAI
Amstel Botel	City Center	tram 4 (direc. RAI) to RAI
Avenue	City Center	tram 4 (direc. RAI) to RAI
Bellevue	City Center	tram 4 (direc. RAI) to RAI
Best Western Beethoven	5-10 min by Taxi	tram 5 (direc. Amstelveen Binnenhof) to station Zuid, change to metro 50 (direc. Gein) or metro 51 (direc. Central Station) to RAI
Best Western Eden	City Center	tram 4 (direc. RAI) to RAI
Best Western Lancaster	City Center	tram 9 (direc. Centraal Station) or tram 14 (direc. Slotermeer) to Rembrandtplein, change to tram 4 (direc. RAI) to RAI
Bastion Hotel Amsterdam Amstel	5-10 min by Taxi	metro 51 (direc. Amstelveen Westwijk) to RAI
Bastion Hotel Amsterdam Zuidwest	Outskirts of Amsterdam	metro 50 (direc. Gein) to RAI
Europa 92	City Center	tram 12 (direc. Amstel station) to Victorieplein, change to tram 4 (direc. RAI) to RAI
Hampshire Inn Prinsengracht	City Center	tram 4 (direc. RAI) to RAI
Hotel de Filosoof	City Center	tram 12 (direc. Amstel station) to Victorieplein, change to tram 4 (direc. RAI) to RAI
Hotel V	Walking distance	tram 4 (direc. RAI) to RAI
Ibis Airport	Schiphol area	no tram or bus
Ibis Amsterdam Centre	City Center	tram 4 (direc. RAI) to RAI
Ibis Amsterdam Stopera	City Center	metro 51 (direc. Amstelveen Westwijk) to RAI
Ibis Amsterdam Westcorner	Outskirts of Amsterdam	metro 50 (direc. Gein) to RAI
Leidse Square	City Center	tram 7 (direc. Flevopark) or tram 10 (direc. Azartplein) to Frederiksplein, change to tram 4 (direc. RAI) to RAI
NH city centre	City Center	tram 4 (direc. RAI) to RAI
Owl Hotel	City Center	tram 12 (direc. Amstel station) to Victorieplein, change to tram 4 (direc. RAI) to RAI
Ramada city centre	City Center	tram 4 (direc. RAI) to RAI
Tulip Inn City West	Outskirts of Amsterdam	tram 17 (direc. Central Station) to station Lelylaan, from here metro 50 (direc. Gein)
Tulip Inn Amsterdam Centre	Walking distance	tram 4 (direc. RAI) to RAI

Award Winners

Ole J. Bjerrum

After finishing his medical internship, Ole J. Bjerrum (MD, DMSc) joined the Protein Laboratory at the Medical Faculty, University of Copenhagen as Assistant Professor (1970-1974), and as Associate Professor (1974-1987). In this period he served five years as director of the laboratory. Further to this, Ole J. Bjerrum has 14 years of industrial experience at Novo Nordisk, first as Director of Biolabs (a diagnostic unit), after that as senior principal scientist at Bioscience (working on various aspects of drug discovery, including HTS), and finally as liaison officer between the company and academia and national and international research organisations. In the period 1989-99 he was Adjunct professor in Immunotechnology at the Technical University of Denmark. From August 1, 2001, he is Professor of Pharmacology at the Danish University of Pharmaceutical Sciences, from 2007 on the University of Copenhagen Scientifically Ole J. Bjerrum has been engaged in the analysis and characterisation of membrane receptors and transporters, employing electrophoresis and immunotechnology tools (thesis 1977). Lately, his interest has been in in vitro and *in vivo* pharmacology aspects of chronic pain conditions. His publication list covers 3 books and more than 135 peer reviewed scientific papers.

Ole J. Bjerrum is a Fellow of the Danish Academies of Technical Sciences and Natural Sciences, respectively. He served as member of the Danish Medical Research Council and of the European Science and Technology Assembly, as well as of the EU Commission 4th and 5th Framework Programme Committee on Biotechnology and Quality of Life, respectively. In addition, he was co-founder of the Centre for Proteome Analysis, University of Southern Denmark. He was associated with the Centre as Adjunct professor from 1999 - 2004.

In 1998, Ole J. Bjerrum joined the EUFEPS Committee on Industrial Relations (CIR). In 1999 he became member of the Executive Committee and served from 2000 as President-elect, from 2003 as President and from 2005 as Immediate past-president. He has taken an interest to promote the pharmaceutical sciences in Europe, through initiatives such as the formulation of the theme: New Safe Medicines Faster. An initiative which has had significant impact on the EU 6th Framework Programme for 2003-2007 and which paved the way for the Joint Technology Initiative: Innovative Medicines in the 7th Framework Programme.

William N. Charman

Prof Bill Charman is Dean, Victorian College of Pharmacy, Monash University in Melbourne, Australia. He received his PhD in pharmaceutical chemistry from the University of Kansas in 1985, and from 1986-1989 was a Senior Scientist/Group Leader at the former Sterling-Winthrop Research Institute in Rennselear New York. He returned to Australia in 1989 where his research interests include enhanced absorption and bioavailability of poorly water soluble drugs, lymphatic drug transport, lead candidate optimisation, and the discovery and development of drugs for neglected diseases. He received the GlaxoWellcome International Achievement award in Pharmaceutical Sciences from the Royal Pharmaceutical Society of Great Britain in 1999, the Drug Discovery Project of the Year by the Medicines for Malaria Venture (Geneva, Switzerland) in 2002, the APSA medal in 2005, and the Controlled Release Society international career achievement in oral drug delivery in 2006. He has published over 330 scientific papers and communications, is a member of four international Editorial Boards, and is an Associate Editor of the Journal of Pharmaceutical Sciences. He is an elected Fellow of the American Association of Pharmaceutical Scientists, a previous member of two Corporate Boards, a member of various Scientific Advisory Boards and is Chairman, Seeding Drug Discovery Funding Committee of the Wellcome Trust.

Alfonso Domínguez-Gil Hurlé

Dr. Alfonso Domínguez-Gil Hurlé was born in Gijón (Spain) in 1942. He received a fellowship from the Research Personnel Training Programme of the Spanish Ministry of Education (1968-1971), later receiving a PhD (with Extraordinary Prize). Since 1974 he has been Full professor of Pharmacy and Pharmaceutical Technology at the University of Salamanca (Spain). Currently, he is Professor of Biopharmacy and Clinical Pharmacokinetics. He was the Director of the Department of Pharmacy and Pharmaceutical Technology, Dean of the School of Pharmacy and Vice-Rector responsible for Investigation of the University of Salamanca (1980-1985). He has been a specialist in Hospital Pharmacy since 1975. Currently, he directs the Pharmaceutical Services of the University Teaching Hospital in Salamanca. He has been Director of the specialist courses entitled "Therapeutic Drug Monitoring" run since 1982, of which there have been 24 annual gatherings, attended by 1,800 pharmacists and physicians from Spain, France, Italy, Mexico, Chile, etc. He has delivered many specialist courses dealing with Clinical Pharmacokinetics in Spanish and non-Spanish Universities and at meetings of Spanish Scientific Societies: Hospital Pharmacy, Nephrology, Intensive Care, Chemotherapy, etc.

Dr. Domínguez-Gil Hurlé is the author of more than 300 publications concerning clinical

pharmacokinetics and pharmacoeconomy published in international journals. He has delivered more than 200 scientific contributions at Spanish and international meetings. He has participated in 32 clinical pharmacokinetic studies. He currently directs the Unit of Clinical Pharmacokinetics and Pharmaceutical Care for HIV-Positive Patients of the University Teaching Hospital in Salamanca. He is the co-author of the Spanish-English/English Spanish Terminological Dictionary of the Pharmaceutical Sciences published by the Royal Spanish Academy of Pharmacy (2007). He has authored 10 books addressing Hospital Pharmacy and Clinical Pharmacokinetics published in Spain, the United Kingdom and the United States. He has represented Spain at the European Pharmacopoeia of the European Council in Strasburg and at the International Pharmacopoeia in Geneva; he has been President of the Commission of the Royal Spanish Pharmacopoeia (200-2004) and a member of the Scientific Council the Spanish Drugs Agency. He has been Vice-President of the Spanish Society of Pharmacology and a member of the Spanish Agency for Quality Assessment of Universities and of the Spanish Teaching-staff Accreditation Agency in the area of the Health Sciences. He is a member of the Quality Assessment Committee of Pharmacy Schools in Portugal. Currently he is a member of the Quality Agency of the Universities of the Balearic Islands (Spain). Since 1980, he has been President of the Pharmacy and Therapeutics Commission of the University Teaching Hospital in Salamanca and Vice-President of the Ethical Committee for Clinical Research. Since 1998 he has been the Director of the Institute for Safe Medication Practices (Spain), a delegation of the ISMP in the United States. He has received many awards and distinctions, among them the Laude Award for Pharmaceutical Investigation (Spain) in 1974 and the Award of the American Society of Hospital Pharmacy Research and Education Foundation (1994). He represented Spain in the constitution of the Iberian-Latin-American Association of Pharmacy Academies held in Valparaiso (Chile) in 2005. Dr. Domínguez-Gil Hurlé is a member of the Scientific Committee of the Spanish Foundation of Drug Sciences, and belongs to the following Academies: the Royal Spanish Academy of Pharmacy; The Royal Academy of Medicine of Salamanca, The Royal Spanish Academy of Pharmacy in Catalonia (Spain), and the Academy of Pharmacy of Galicia (Spain).

Elias Fattal

Elias Fattal is a Full Professor of Pharmaceutical Technology at the University of Paris-XI in Châtenay-Malabry, France and has been President of APGI since 2003. He received his Pharmacy Degree (1983), and Ph.D. (1990) from the University of Paris-XI. After visiting the Department of Pharmaceutical Chemistry, University of California, San Francisco for a post-doctoral position with Frank Szoka (1990-1991), he became associate Professor (1992) and full Professor at the University of Paris-XI (2000). Elias Fattal is leading the research group "Drug targeting and delivery of poorly stable drugs" in the CNRS research unit UMR CNRS 8612. He is also vice-chair of this department. His research activity deals with the design of nano- and microtechnological approaches for the delivery of peptides/proteins and nucleic acids. His special expertise deals with oral administration of proteins and vaccines and the design of delivery systems for antisense oligonucleotides. Special attention was given in recent years to the ocular delivery of nucleic acids and the use of cyclodextrins as absorption enhancing agents. He is the author and co-author of around 135 publications and book chapters and 10 patents. In 1999, he received the Colloidal Drug Carrier Award (at the 5th Expert meeting on colloidal drug carriers, Berlin, Germany). Elias Fattal is the co-editor of the Journal of Drug Delivery Science and Technology, the European editor of the Journal of Biomedical Nanotechnology. He serves on the editorial board of several pharmaceutical journals (Journal of Pharmaceutical Sciences, European Journal of Pharmaceutical Sciences, American Journal of Drug Delivery, and Expert Opinion on Drug Delivery) and nanotechnology dedicated journals (NanoBiotechnology, International Journal of Nanomedicine).

Kathleen M. Giacomini

Dr. Kathy Giacomini is Professor and Chair of Biopharmaceutical Sciences at the University of California, San Francisco. She received her Ph.D. in Pharmaceutics from the State University of New York at Buffalo and completed a post-doctoral fellowship at Stanford University. Dr. Giacomini is considered a leader in the field of pharmacogenomics of membrane transporters. She led the discovery of coding region variants of about 50 membrane transporters that play a role in drug response in ethnically diverse populations. Dr. Giacomini and her group functionally characterized over 100 transporter variants in cells, discovering both gain of function and loss of function variants that may lead to variation in drug response. She has received numerous awards for her research and teaching including the Dawson Award of the American Association of Colleges of Pharmacy and the Research Achievement Award in Drug Metabolism from the American Association of Pharmaceutical Scientists. In 2006, she was elected to the Institute of Medicine of the National Academies.

Hans E. Junginger

H.E. Junginger, Ph.D. was Professor of Pharmaceutics and Head of the Division of Pharmaceutical Technology at the Leiden/Amsterdam Center for Drug Research, Leiden University, The Netherlands until 1 February 2004 when he took early retirement

Since 1 January 2004 he is a guest professor at the Faculty of Pharmaceutical Sciences, Naresuan University, Phitsanulok, in Thailand and since 2005 also a Visiting Professor at the National University of Singapore and at the Pharmacy Department of Ljubljana in Slovenia.

He qualified as a pharmacist in 1967, at the University of Munich, Germany. In 1971, he obtained his Ph.D. degree in Pharmaceutical Chemistry at the University of Saarbr_cken, Germany. From 1972 to 1980 he worked as a researcher at the Technical University of Braunschweig, Germany to obtain his qualification as professor in Pharmaceutical Technology. From 1980 to 2004 he was the Head of the Department of Pharmaceutical Technology at the Leiden/Amsterdam Center for Drug Research, The Netherlands.

He has published more than 280 articles and 35 book chapters. He is the (co)inventor of 8 patents.

His main research areas included the development of novel controlled drug delivery systems (especially for peptide drugs) for the (trans)dermal and peroral routes, utilizing new (bioadhesive) polymers. Especially, multifunctional polymers as polyacrylates and chitosan derivatives have been identified to be safe and non-toxic penetration enhancers for hydrophilic drugs. Furthermore, they are excellent delivery systems for the nasal, pulmonary and oral route for peptides, protein and (DNA) vaccines. Combining superporous hydrogels or other expanding tablet systems with those multifunctional polymers make the oral absorption of peptides feasible.

Until now 52 Ph.D. students have graduated under his supervision and 25 post-docs from all over the world joined his department in Leiden.

Between 1986 until 1990 he was president of the International Association for Pharmaceutical Technology (APV) and in 1994/5 president of the Controlled Release Society.

He was the Scientific Secretary of the International Pharmaceutical Federation FIP (1995 – 2003) and as such member of the Executive Committee of FIP.

He has received several major awards and three honorary doctorates (Ghent, Belgium in 1995, Potchefstroom University in South Africa in 2003 and London University, UK in 2004).

He is a frequently invited speaker at international conferences and a consultant to international pharmaceutical industries.

He loves traveling and as result of this his nickname is "Flying Dutchman". When at home he loves to play piano and to read criminal stories.

Kevin Shakesheff

Kevin Shakesheff is Professor of Tissue Engineering at the University of Nottingham. He is a registered Pharmacist and trained within the NHS as part of his professional qualification in 1992. After obtaining a PhD in polymer science, he moved to the Massachusetts Institute of Technology in the mid 1990s to work on polymers used in tissue engineering. In 1997, he returned to the UK to take up an Engineering and Physical Sciences Research Council Advanced Fellowship. In recent years, he has been named as one of the World's top Young Innovators by MIT's Technology Review, won the 2004 Hanson Award and presented his work at the Royal Insitution under the "Scientists for a New Century" series. He was co-founder of the Tissue and Cell Engineering Society and founder of RegenTec Ltd, a biotech company based in Nottingham and developing clinical products based on regenerative medicine.

Scientific highlights of recent work by Professor Shakesheff's team include the demonstration of formation of polymer & cell composites by a novel supercritical fluid processing route (Ginty et al¸PNAS, 2006 in press), the use of plasma polymers to control the distribution of cells in 3D polymer scaffolds (Barry et al, Advanced Functional Materials, 15, 1134-1140, 2005), and the selective modification of cell responses to ECM proteins on scaffolds (De Bank PA et al, Journal of Materials Chemistry 15, 2047-2055, 2005). Our novel scaffold systems are applied in a number of tissue engineering applications including liver (Thomas et al, Cell Tissues Organs 181, 67-79, 2005), skin (Horobin et al, Wound Repair and Regeneration 13, 422-433, 2005), nerve (Teare et al, Neuroreport, 15, 493-498, 2004) and bone (Yang et al, Journal of Bone and Mineral Research, 18, 47-57, 2003).

Yuichi Sugiyama

Yuichi Sugiyama, Ph.D., born in 1947, is Professor and Chairman, Department of Biopharmaceutics at the University of Tokyo since 1991. The Department name was recently changed to Molecular Pharmacokinetics. Except for a sabbatical at UCLA in 1979-1981 with Professor Kaplowitz, he has been at the University of Tokyo throughout his career, receiving a B.S. in Pharmacy in 1971, a Ph.D. in Pharmaceutical Sciences with Professor Hanano in 1978. He is a co-author of more than 480 publications in international journals as well as 270 book chapters and review articles (ca.60 written in English). His research focuses on two areas: 1) Physiologically based pharmacokinetics: prediction of drug dispositions from in vitro biochemical data; 2) Molecular pharmacokinetics of drug transport in liver, kidney, and brain.

Professor Sugiyama's research on membranes has yielded better understanding of the basic aspects of transport mechanisms. He has discovered several examples in which transporters play a major role in drug disposition by integrating in vitro data with *in vivo* pharmacokinetic models. Moreover, his work has highlighted the importance of considering pharmacokinetic properties in drug development, using screening methods to test large numbers of drug candidates. Detailed in vitro studies of transporters for the first time appear to predict transporter-mediated drug-drug interaction *in vivo*. Analysis of genetic poly-

morphisms in transporter genes are being identified in his laboratory that can account for inter-individual differences in drug disposition. Overall, he has produced a body of scientific work with an impact on our understanding of how drugs work and how to use them.

His work is internationally recognized receiving several awards, including the Ebert Prize of the American Association of Pharmaceutical Scientists (AAPS) in 1985; Takeru-Aya Higuchi Prize in 1990; Pharmaceutical Scientist of the Year Award of the International Pharmaceutical Federation (FIP) in 1994; the Scientific Achievement Award from the Academy of Pharmaceutical Science and Technology, Japan (APSTJ) in 1995; the Scientific Achievement Award from the "Japanese Society for Xenobiotic Metabolism and Disposition (JSSX) " in 2001., The Troy C. Daniels Lectureship from UCSF in 2001; the AAPS Distinguished Pharmaceutical Scientist Award in 2003; the Scientific Achievement Award 2004 from the "Pharmaceutical Society of Japan(PSJ)" and the John G. Wagner Pfizer Lectureship Award in Pharmaceutical Sciences from University of Michigan in 2005. According to the information on the website of ISI Essential Science Indicators (ESI), Thomson ScientificÅiUSAÅj, Prof. Sugiyama achieved the 2nd top position for the number of citations for the last 10 years (Jan 1, 1995 - Aug 31, 2005) in the field of "Pharmacology & Toxicology". He is currently the president of both the "International Society for the Study of Xenobiotics (ISSX)" and the "Japanese Society for Xenobiotic Metabolism and Disposition (JSSX)".

He is/was an editorial board member of several international journals, especially editor in Japan of "Pharmaceutical Research" (1992-1996) and "AAPS Pharm. Sci." (1999-2001). He served as the chairman of the Board of Pharmaceutical Sciences of FIP (2000-2004) as the successor of Dr. Leslie Benet. As a program co-chair, he was a main contributor to the success of the Millennial World Congress of Pharmaceutical Sciences, San Francisco 2000, and further, he chaired the "Pharmaceutical Sciences World Conference", Kyoto, Japan, in 2004. (organized by FIP Board of Pharmaceutical Sciences). He was the President of the Academy of Pharmaceutical Science and Technology, Japan (APSTJ) (2002-2003).

Hiroshi Terada

Dr. Hiroshi Terada, Professor at Tokyo University of Science, is an outstanding scientist in the fields of pharmaceutical sciences and biochemistry. Recently, he took an interest in studying controlled drug delivery formulations, especially those for overcoming infectious diseases.

For a long time, prof. Terada has been a Council Member of FIP, representing the PSJ. He was a co-chair of the Pharmaceutical Sciences World Congress (PSWC2004) in Kyoto. He made every effort to promote PSJ to become a member of FIP when he was a board member of PSJ, and then consistently supported the FIP activity when he was President of PSJ.

Vladimir P. Torchilin

Vladimir P. Torchilin, Ph.D., D.Sc. is a Distinguished Professor and Chair of the Department of Pharmaceutical Sciences and Director, Center for Pharmaceutical Biotechnology and Nanomedicine, Northeastern University, Boston, Mass. He graduated from the Moscow State University with a MS in Chemistry, and also obtained there his Ph.D. and D.Sc. in Polymer Chemistry, Chemical Kinetics and Catalysis, and Chemistry of Physiologically Active Compounds in 1971 and 1980, respectively. In 1991 Dr. Torchilin joined the Massachusetts General Hospital and Harvard Medical School as the Head of Chemistry Program, Center for Imaging and Pharmaceutical Research, and Associate Professor of Radiology. Since 1998 Dr. Torchilin is with Northeastern University. His research interests have focused on biomedical polymers, polymeric drugs, immobilized medicinal enzymes, drug delivery and targeting, pharmaceutical nanocarriers for diagnostic and therapeutic agents, and experimental cancer immunology. He has published more than 300 original papers, more than 100 reviews and book chapters, wrote and edited 10 books, made over 250 invited lectures and seminars and holds more that 40 patents. He served on multiple NIH Study Sections and is on the Editorial Boards of many leading journals including Journal of Controlled Release (Review Editor), Bioconjugate Chemistry, Advanced Drug Delivery Reviews, European Journal of Pharmaceutics and Biopharmaceutics, Journal of Drug Targeting, Molecular Pharmaceutics, Journal of Biomedical Nanotechnology, and many others. Among his many awards, Professor Torchilin was the recipient of the 1982 Lenin Prize in Science and Technology (the highest scientific award in the former USSR).

He was elected as a Member of the Russian Academy of Biotechnology and the European Academy of Sciences. He is also a Fellow of the American Institute of Medical and Biological Engineering and of the American Association of Pharmaceutical Sciences and received the 2005 Research Achievements in Pharmaceutics and Drug Delivery Award from the AAPS. He is on the Board of Directors of the International Liposome Society, and in 2005-2006 he served as a President of the Controlled Release Society.

Post-Satellite Workshop
of the 3rd Pharmaceutical Sciences World Congress (PSWC2007)

Monoclonal Antibodies

April 26-27 • 2007 • Amsterdam • The Netherlands

Scope and Aim

Monoclonal antibodies are one of the most important classes of therapeutic recombinant proteins. They are under clinical evaluation for a broad range of important therapeutic areas including cancer, rheumatoid arthritis and infectious diseases. Classical Biotech companies are no longer the only players and traditional large Pharma companies have now also recognised the potential of recombinantly manufactured monoclonal antibodies.

This Workshop will cover a broad spectrum of topics from the design and engineering of monoclonal antibodies, through process development (e.g. cell line optimisation and down stream processing), analytics, formulation aspects and manufacturing up to clinical applications. An important element of the Workshop will be the attention paid to current regulatory requirements for the introduction of monoclonal antibodies. Trends towards modification of antibodies by conjugation or subsequent glycosylation as well as their reduction in size to antibody fragments such as domain or single chain antibodies will also be discussed.

Location

Hotel Park Plaza Victoria Amsterdam, Damrak 1-5, 1012 LG Amsterdam.

Additional Information

Consult the PSWC2007 Website, the EAPB Website or the EUFEPS Online.

Scientific Planning Committee

Karoline Bechtold-Peters, Boehringer Ingelheim, Germany, Co-chair
Wim Jiskoot, Leiden/Amsterdam Center for Drug Research (LACDR), Co-chair
Daan J.A. Crommelin, Dutch Top Institute Pharma, The Netherlands
Barry Moore, XstalBio, United Kingdom
Wayne Gombotz, Omeros Corp., USA
Jan van de Winkel, Genmab, The Netherlands
Sven Stegemann, Capsugel, Belgium

Registration

For Registration on line access the Workshop web site of the EUFEPS Online at: www.eufeps.org or report to the EUFEPS booth at the PSWC2007.

EAPB www.eapb.org
EAPB is a professional association dedicated to the advancement of biotechnology in pharmaceutical sciences, specifically as applied to industrial materials, processes, products and their associated challenges. Its members constitute scientists employed in industry, government and university laboratories, biotech companies and scientific organisations.

EUFEPS www.eufeps.org
Founded in 1991, the mission of EUFEPS is to advance excellence in the pharmaceutical sciences and innovative drug research, and to represent the interests of scientists engaged in drug research and development, drug regulation and drug policymaking. Currently, EUFEPS links 24 Member Societies in 24 European countries.

AAPS www.aaps.org
AAPS is a professional scientific society of more than 12,000 members employed in academia, industry, government and other research institutes worldwide. Founded in 1986, AAPS provides a dynamic international forum for the exchange of knowledge among scientists to enhance their contributions to public health.

FIP www.fip.org
FIP, founded in The Hague, more than 90 years ago, is the worldwide federation of national pharmaceutical, professional and scientific, associations, with a mission to represent and serve pharmacy and pharmaceutical sciences around the globe. Through its member association, FIP connects, represents and serves more than a million pharmacists and pharmaceutical scientists around the world.

Organisers and Co-sponsors

Organisers of this PSWC 2007 Post-Satellite are the European Association of Pharma Biotechnology (EABP) and the European Federation for Pharmaceutical Sciences (EUFEPS), and it is co-sponsored by the American Association of Pharmaceutical Scientists (AAPS) and the International Pharmaceutical Federation (FIP).

Thursday • April 26, 2007

Welcome, Introduction and Opening Remarks

Keynote Presentation: Past, Present and Future of Antibody Therapeutics
Sir Gregory Winter, University of Cambridge, UK

Session I: New technologies for design of antibodies and engineering
Chairman: *Jan GJ van de Winkel,* Genmab, NL

Glycoengineered therapeutic antibodies with increased FcgRIII binding affinity and enhanced biological activity
Peter Brünker, F Hoffmann - La Roche, Schlieren - Zürich, CH

Engineering antibody effector funtion
Carl Webster, Cambridge Antibody Technology, UK

Generating novel immuno-therapeutics for small bioactive compounds (haptens)
Andy Porter, Haptogen, UK

Session II: Latest advancements in upstream development including expression systems and feed strategies
Chairman: *Sven Stegemann*, Capsugel, BE

Manufacturing therapeutic monoclonal antibodies in chicken eggs
Marie-Cecile van de Lavoir, Origen Therapeutics, Burlingame CA USA

Qualitative and quantitative comparison of protein expression systems for the manufacturing of antibodies
Rainer Fischer, Fraunhofer-Institut für Molekularbiologie und Angewandte Oekologie, DE

Cell culture points-to-consider: A commercial perspective
Ben Bulthuis, Centocor, NL

Session III: Downstream development including purification and recovery optimisation
Chairman: *Karoline Bechtold-Peters*, Boehringer-Ingelheim, DE

Economic considerations for disposable technologies in antibody manufacturing
Uwe Gottschalk, Sartorius, DE

Challenges in the development of economic and robust downstream processes for therapeutic antibodies using platform technologies
Alexander Jacobi, Boehringer Ingelheim Pharma GmbH & Co. KG, DE

Controlled freeze-thaw technology
Gaël Péron, Stedim Biosystems, FR

Session IV: Physical characterisation, formulation and delivery systems
Chairmen: *Barry Moore*, XstalBio, UK, and *Wim Jiskoot*, Leiden/Amsterdam Center for drug Research (LACDR), NL

Rapid physical characterisation tools for biopharmaceuticals as used in the early development phase
Patrick Garidel, Boehringer-Ingelheim, DE

High concentration processing and formulation of Mabs – New and state-of-the-art approaches
Wolfgang Friess, University of Munich, DE

Novel dry powder antibody formulations
Jan Vos, XstalBio, UK

Analytical challenges addressed
Tudor Arvinte, University of Geneva, CH

Session V: Analytics and specs
Chairman: *Daan JA Crommelin,* Top Institute Pharma, NL

Setting specifications for Mabs - Regulatory perspective
Bernd Liedert, Paul Erlich Institute, DE

Application of analytical ultracentrifugation as an orthogonal method for protein size distribution analysis
James Andya, Genentech Inc., South San Francisco CA USA

Aggregates in biotech products - Regulatory expectations for aggregates
Elizabeth Leininger, StemCells Inc, Palo Alto CA USA

End of day I and panel discussion

Friday • April 27, 2007

Session VI: Scale-up issues and production scale manufacturing
Chairman: *Wayne Gombotz,* Omeros Corporation, Seattle WA USA

How to make successful technology transfers in Mabs production
Tim Clayton, Laboratoires Serono SA, CH

Integrated downstream process design in Mabs production – The white knight to slay the cost dragon?
Jochen Strube, Clausthal University of Technology, DE

Production of human monoclonal antibodies on the human cell-line PER.C6
Erik Hack, Crucell, NL

Session VII: Clinical update (new antibody therapies), commercial impact and new trends
Chairman: *Jan GJ van de Winkel,* Genmab, NL

Anti-IL12p40 antibody development and clinical data
Trudi Veldman, Abbott, USA

Ofatumumab, a novel human CD20 antibody for treatment of lymphoid malignancies and inflammation
Jan GJ van de Winkel, Genmab, NL

Commercial impact and potential of Mab products and Mab production
Andreas Werner, Boehringer Ingelheim, DE

The next generation of recombinant immunotoxins
Stefan Barth, Fraunhofer-Institut IME-MB, DE

Session VIII: Pharmacokinetics and safety
Chairman: *Wim Jiskoot,* Leiden/Amsterdam Center for Drug Research (LACDR), NL

Clinical consequences of development of antibodies to therapeutic monoclonal antibodies
Lucien Aarden, Sanquin, NL

Global immunogenicity assessment of antibody therapeutics
Philippe Stas, Algonomics, BE

Safety assessment of monoclonal antibody products – Perspective on preclinical requirements to support the determination of safe use conditions
James D Green, Biogen Idec Inc, Cambridge MA USA

Session IX: Armed antibodies and new classes of antibodies or antibody derivatives
Chairman: *Wayne Gombotz,* Omeros Corp., USA

Conjugated antibodies – Overview and case study on Mylotarg
Boris Gorovits, Wyeth, USA

UniBody: A novel human antibody-based platform for immunotherapy
Paul Parren, Genmab, NL

Potent immunoconjugates for cancer therapy
Peter Senter, Seattle Genetics, USA

Discussion Forum: Future of antibody therapeutics/what are the next steps?
(Prepared questions, participants to forward questions on cards, panel discussion)

Sponsors

Pre-Satellite Meeting
of the 3rd Pharmaceutical Sciences World Congress (PSWC2007)

Young Pharmaceutical Scientists Meet in Amsterdam

Scope and Aim

The Pharmaceutical Sciences World Congress 2007 is pleased to offer a pre-satellite symposium dedicated to the next generation of pharmaceutical scientists. Doctorate students and postdoctorate fellows from all over the world convene in Amsterdam to exchange ideas and discuss the latest developments in pharmaceutical sciences.

During the one and a half day event, young scientists present lectures in parallel sessions on such topics as: Target Discovery/Medicinal Chemistry, Pharmacokinetics / Pharmacodynamics, Drug Delivery, Pharmaceutical Analysis / Bioanalysis / Quality Assurance / Regulatory Affairs, Clinical Pharmacy / Pharmacoepidemiology and Toxicology / Safety. In addition, poster presentations are held on the latest research findings in all fields of pharmaceutical sciences. The students/postdoctoral fellows have the opportunity to present their work during "poster walks".

In each scientific section, the most outstanding poster presentation is honored with a "Young Investigator Award". Keynote lecturers in all areas give comprehensive overviews on the current developments in their particular fields. This pre-satellite meeting gives young pharmaceutical scientists the unique opportunity to network and share professional experiences before the start of the 3rd Pharmaceutical Sciences World Congress on April 22, 2007.

Location

University of Amsterdam (*Vrije* Universiteit Amsterdam) De Boelelaan 1105, NL-1081 HV Amsterdam, The Netherlands.

Social Programme

Saturday afternoon: Amsterdam tour by foot and boat

Saturday night: Pre-satellite party

Boom Chicago Show, including 3 course dinner and drinks

Organising Committee

S.C. De Smedt (Chair); *P. Augustijns; J. Commandeur; D.J.A. Crommelin; M. Danhof; G.J. De Jong; S. Deferme; J. Demeester; W. Hennink; U. Holzgrabe; O. Klungel; C.M. Lehr; H.H. Linden; E. Mastrobattista; R. Schiffelers; F. Siepmann; J. Siepmann; N.P.E. Vermeulen;* and *B.H. Westerink*

Vrije Universiteit Amsterdam, Amsterdam, The Netherlands
April 20 and 21, 2007

PROGRAMME

Friday, April 20, 2007	
09:00 - 09:15	**Introduction**
09:15 - 09:40	**Key note lecture I** Pharmacogenetics and regulation of human cytochromes (*Dr. C. Rodriguez-Antona*)
09:40 - 10:05	**Key note lecture II** Non-viral gene delivery (*Dr. N. Kobayashi*)
10:05 - 10:30	**Key note lecture III** HIV entry inhibitors: ligand-based design of peptidomimetic CXCR4 antagonists (*Dr. J. Vabeno*)
10:30 - 11:00	Coffee break
11:00 - 12:30	**Oral session I** ■ TD/MC ■ DM/DT/Tox-Saf ■ DD Techno ■ PA/QA/RA ■ CP/PK-PD/PE ■ DD Bio
12:30 - 14:00	Lunch and poster viewing
14:00 - 15:30	**Oral session II** ■ TD/MC ■ DM/DT/Tox-Saf ■ DD Techno (1) ■ DD Techno (2) ■ CP/PK-PD/PE ■ DD Bio
15:30 - 16:00	Coffee break
16:00 - 17:00	**Oral session III** ■ TD/MC ■ DD Techno ■ PA/QA/RA ■ CP/PK-PD/PE (1) ■ CP/PK-PD/PE (2) ■ DD Bio
17:00 - 19:00	Poster walk - wine & cheese buffet

Saturday, April 21, 2007	
09:15 - 09:40	**Key note lecture IV** Peptide mapping of biofluids by multidimensional LC/MALDI-TOF MS (*Dr. E. Machtejevas*)
09:40 - 10:05	**Key note lecture V** Gene expression profiling and breast cancer care (*Dr. N. Oestreicher*)
10:05 - 10:30	**Key note lecture VI** Mechanism-based PK-PD modelling of drug efficacy and safety: application to (semi)-synthetic opioids (*Dr. A. Yassan*)
10.:30 - 10:45	Poster and Galenos award ceremony
10:45 - 11:15	Coffee break
11:15 - 12:45	**Oral session IV** ■ TD/MC ■ DM/DT/Tox-Saf ■ DD Techno ■ CP/PK-PD/PE ■ DD Bio
12:45 - 14:00	Closing of the scientific programme / lunch
14:00 - 16:00	**Interactive Author Seminar** How to write and submit a world-class paper

TD/MC: Target discovery/Medicinal chemistry; DM/DT/Tox-Saf: Drug metabolism/Drug transport/Toxicology-Safety; DD Techno: Drug delivery-Technology; PA/QA/RA: Pharmaceutical analysis/Quality assurance/Regulatory affairs; CP/PK-PD/PE: Clinical pharmacy/Pharmacokinetics-Pharmacodynamics/Pharmacoepidemiology; DD Bio: Drug delivery-Biology.

Sponsors

Visit our website: http://pharmacie.univ-lille2.fr/presatellitePSWC

Pre-Satellite Workshop
of the 3rd Pharmaceutical Sciences World Congress (PSWC2007)

Pharmaceutical Curriculum Development: An evolutionary or a revolutionary process?

Saturday, April 21, 2007
Department of Pharmaceutical Sciences, Faculty of Science, Sorbonnelaan 16, Utrecht

Education Symposium

Over the past several years, pharmacy curricula across the globe have come under the influence of many developments. The explosion of biomedical and pharmaceutical knowledge brought with the unravelling of the human genome, coupled with greater societal needs and expectations placed on pharmacists by an increasingly complex healthcare system, has required changes in the way pharmacists are trained and the skills they bring to the healthcare circle. Competency based education with an emphasis on patient-oriented practice and accountability are the current and future trends in pharmacy education.

Worldwide pharmacy schools face a tremendous challenge in rapidly adapting to these exciting yet sometimes conflicting developments. The intention of the PSWC Education Symposium is to bring together pharmaceutical scientists active in academia to discuss these challenges, possible solutions, and of course the biggest dilemma: How to promote state-of the-art pharmaceutical sciences in curricula when at the same time there is a great societal demand to shift from product-oriented to patient-oriented pharmacy education and practice.

The programme will consist of plenary lectures and round table discussions, offering ample opportunity for interaction. In addition, participants are invited to join in a guided tour of the Dept. of Pharmaceutical Sciences in Utrecht, a Department which has recently seen a radical change in its curriculum and organisational structure focussing on problem-oriented and student centred educational methods, in order to optimally prepare future practitioners and scientists.

For whom?

Academic colleagues who are interested in pharmaceutical curriculum development in particular for 6 years programmes.

How do delegates get there?

Bus transport to Utrecht will leave at 9:00 hrs sharp! in front of: Hotel Novotel Amsterdam, Europaboulevard 10, Amsterdam.

A hostess/student with the sign "Workshop: Pharmaceutical Curriculum Development: an evolutionary or a revolutionary process?" will be present on the spot to guide the delegates.

After the satellite, there is bus transport back to Hotel Novotel in Amsterdam.

Programme

Welcome by *Bert Leufkens*, Dean of the Department of Pharmaceutical Sciences
Anthonius de Boer and *Andries Koster* Department of Pharmaceutical Sciences, Utrecht, the Netherlands *Radical changes of a pharmacy curriculum*
Tetsumi Irie Faculty of Medical and Pharmaceutical Sciences, Kumamoto, Japan *New six-year pharmacy curricula in Japan*
Fe-Lin Lin Wu School of Pharmacy, Taipei, China Taiwan *Evolution of pharmacy education in Taiwan*
Lunch and guided tour through Education Center of the Department of Pharmaceutical Sciences
Kyenghee Kwon College of Pharmacy, Seoul, Korea *The new era of the pharmacy education in Korea: How could we move from subject orientation to professional goals?*
Ian Bates School of Pharmacy, London, United Kingdom *Is it possible to maintain the science base whilst increasing a patient orientation in pharmacy curricula?*
Round Table Discussions

Post-Satellite Symposium
of the 3rd Pharmaceutical Sciences World Congress (PSWC2007)

Microdialysis: The Target Site in Focus

April 26-28, 2007, Leiden, The Netherlands

Prediction of drug target site distribution and effects is of utmost importance for successful drug development. In the last decades a number of useful *in vivo* monitoring techniques have been become available, like PET, NMR and microdialysis. The unique characteristic of *in vivo* microdialysis is that it provides specific information on the extracellular tissue space, which represents the target site of many drugs, but also is the space in which the biochemical events may serve as biomarkers of the drug effects or on a pathological process. This makes that *in vivo* microdialysis has gained a special position within Drug Research and Development. Its potential is continuously growing by gain of insight in microdialysis experimentation, together with the improvement of analytical methodologies able to deal with the typical small-volume-low-concentration samples.

This Symposium will deal with discussions and exchange of knowledge on the latest developments of the role and potential of *in vivo* microdialysis complementary to other techniques and approaches to increase drug candidate selection efficiency, on the basis of the following workshops:

- Methodological Advances and Considerations in Monitoring the Extracellular Space
- Preclinical and Clinical Pharmacokinetics and Target Site Distribution
- Pharmacokinetic – Pharmacodynamic Correlations
- Monitoring Biomarkers and Drug Penetration in Disease Conditions

Organizing Committee:

- Elizabeth CM de Lange, Chair
- Meindert Danhof
- Martha van der ham
- Erik de Vries

More information is available at www.lacdr.nl

Leiden / Amsterdam Center for Drug Research

Leiden University/Vrije Universiteit Amsterdam

INTERNATIONAL PHARMACEUTICAL FEDERATION FIP

EUFEPS EUROPEAN FEDERATION FOR PHARMACEUTICAL SCIENCES

Poster Overview and Abstract Listing

Poster Overview during PSWC2007 in Hall 10, RAI Amsterdam			
Monday, April 23, 2007	317 posters		Please, note!
CP-M-001	CP-M-013	PSWC: Clinical Pharmacology and Biomarkers	07:30-08:30 hang up poster 11:15-12:15 author at board 17:00- 18:00 take down posters 18:00-19:00 change numbers
DMT-M-001	DMT-M-031	PSWC: Drug Metabolism and Transport	
DD-M-001	DD-M-157	PSWC: Formulation, Delivery, Biopharmaceutics and Pharmaceutical Technology	
MC-M-001	MC-M-043	PSWC: Medicinal Chemistry and Natural Products	
PA-M-001	PA-M-020	PSWC: Pharmaceutical Analysis, Bioanalysis, Quality Assurance/Control and Regulatory Affairs	
PE-M-001	PE-M-015	PSWC: Pharmacoepidemiology and Pharmacovigilance	
KD-M-001	KD-M-025	PSWC: Pharmacokinetics and Pharmacodynamics	
KG-M-001	KG-M-014	PSWC: Pharmacokinetics and Pharmacogenetics	
Tuesday, April 24, 2007	312 posters		Please, note!
CP-T-001	CP-T-012	PSWC: Clinical Pharmacology and Biomarkers	07:30-08:30 hang up poster 11:15-12:15 author at board 17:00- 18:00 take down posters 18:00-19:00 change numbers
DMT-T-001	DMT-T-028	PSWC: Drug Metabolism and Transport	
DD-T-001	DD-T-152	PSWC: Formulation, Delivery, Biopharmaceutics and Pharmaceutical Technology	
MC-T-001	MC-T-035	PSWC: Medicinal Chemistry and Natural Products	
PA-T-001	PA-T-020	PSWC: Pharmaceutical Analysis, Bioanalysis, Quality Assurance/Control and Regulatory Affairs	
PE-T-001	PE-T-015	PSWC: Pharmacoepidemiology and Pharmacovigilance	
KD-T-001	KD-T-025	PSWC: Pharmacokinetics and Pharmacodynamics	
TD-T-001	TD-T-026	PSWC: Target Discovery and Molecular Pharmacology	
Wednesday, April 25, 2007	323 posters		Please, note!
CP-W-001	CP-W-012	PSWC: Clinical Pharmacology and Biomarkers	07:30-08:30 hang up poster 11:15-12:15 author at board 14:00-14:30 take down posters
DMT-W-001	DMT-W-028	PSWC: Drug Metabolism and Transport	
DD-W-001	DD-W-152	PSWC: Formulation, Delivery, Biopharmaceutics and Pharmaceutical Technology	
MC-W-001	MC-W-035	PSWC: Medicinal Chemistry and Natural Products	
PA-W-001	PA-W-021	PSWC: Pharmaceutical Analysis, Bioanalysis, Quality Assurance/Control and Regulatory Affairs	
PE-W-001	PE-W-014	PSWC: Pharmacoepidemiology and Pharmacovigilance	
KD-W-001	KD-W-029	PSWC: Pharmacokinetics and Pharmacodynamics	
TOX-W-001	TOX-W-035	PSWC: Toxicology and Safety Sciences	

All abstract texts can be found on the CD that has been inserted in your Congress Bag

Monday April 23, 2007

Clinical Pharmacology and Biomarkers

CP-M-001
A SIMPLE METHOD FOR PREVENTION OF ADVERSE EFFECTS IN DOUBLE FILTRATION PLASMAPHERESIS (DFPP)
Shinji Abe, Mayumi Torii, Yukie Shimooka, Toshihide Kujime, Kazuhiko Teraoka, Kazuyoshi Kawazoe, Kazuo Minakuchi

CP-M-002
SELECTIVITY OF N-HYDROXYSUCCINIMIDE ESTER-MEDIATED PEPTIDE ACYLATION: APPLICATION FOR THE LABELING OF NITROTYROSINE-CONTAINING PEPTIDES
Nicolas Abello, M. Begona Barroso, Huib A.M. Kerstjens, Dirkje S. Postma, Rainer Bischoff

CP-M-003
BARRIERS TO THE IMPLEMENTATION OF PHARMACEUTICAL CARE IN PSYCHIATRY HOSPITAL IN K.S.A
Khalaf Al-Jumaah, Jawza AL-Sabhan, Zeinab Jaglit

CP-M-004
AN ORAL ADSORBENT, AST-120 PROTECTS AGAINST THE PROGRESSION OF OXIDATIVE STRESS BY REDUCING THE ACCUMULATION OF INDOXYL SULFATE IN THE SYSTEMIC CIRCULATION IN RENAL FAILURE
Makoto Anraku, Kazuki Shimoishi, Yuka Tasaki, Toru Maruyama, Masaki Otagiri

CP-M-005
ACHILLEA SANTOLINA REDUCED OXIDATIVE STRESS IN THE LIVER OF STREPTOZOTOCIN-INDUCED DIABETIC RATS
Amin Ardestani, Razieh Yazdanparast

CP-M-006
IDENTIFYING NONRESPONDERS TO ASTHMA AND COPD THERAPY USING LEUKOCYTE PARAMETERS
Madelon Bracke, Karin Velthove, Madelon Bracke, René Schweizer, Patrick Souverein, Maarten Ten Berg, Bert Leufkens, Wouter Van Solinge

CP-M-007
A MODEL-BASED APPROACH TO BRIDGING PHARMACOKINETICS FROM ADULTS TO CHILDREN.
Massimo Cella, Gijs Santen, Meindert Danhof, Oscar Della Pasqua

CP-M-008
FEMALE HORMONE SECRETION OF TOKI-SHAKUYAKU-SAN (JAPANESE TRADITIONAL MEDICINE) AND RESEARCH ON RELATED GENE EXPRESSION CHANGES: USING OVARIECTOMIZED RATS
Mi Hwa Chung, Masao Hattori

CP-M-009
EFFECT OF SIMVASTATIM MICROEMULSION IN THE TRATMENT OF ABDOMINAL SEPSIS IN WISTAR RATS.
Bolívar P. G. L. Damasceno, Amália C. M. Rêgo, Irami Araújo-Filho, Maria Clara Araújo Silva, Victor Dominici Dominici, Eryvaldo Sócrates Tabosa Egito, Aldo da Cunha Medeiros

CP-M-010
SIMVASTATIN MICROEMULSION FOR CICATRISATION OF INFECTED WOUNDS ON MALE WISTAR RATS
Bolívar P. G. L. Damasceno, Amália C. M. Rêgo, Irami Araújo-Filho, Maria Clara Araújo Silva, Victor Dominici Dominici, Eryvaldo Sócrates Tabosa Egito, Aldo da Cunha Medeiros

CP-M-011
SIMULTANEOUS DETERMINATION OF ACE ACTIVITY WITH TWO SUBSTRATES TELLS US ABOUT THE NATIVITY OF SOMATIC ACE AND ALLOWS TO DETECT ACE INHIBITORS IN HUMAN BLOOD.
Sergei Danilov, Binevski Petr, Balyasnikova Irina, Albrecht Ronald, Kost Olga

CP-M-012
ISOSTEVIOL EFFECTS ON THE CONTRACTIVE AND DILATIVE FUNCTIONS OF THE RABBIT HEART FOLLOWING ISCHEMIA-REPERFUSION INJURY.
Andrew Keith Davey, Deyi Xu, Yongfang Li, Jiping Wang

CP-M-013
LC-MS-MS DETECTION OF CORTICOSTERONE IN DIALYSATES SAMPLED FROM THE INTRACEREBRAL LATERAL VENTRICAL OF THE FREELY MOVING RAT
Alistair Firth, Nick Andrews, Tamar Idle, Hugh Marston, Paul Scullion, Laura Johnston

Drug Metabolism and Transport

DMT-M-001
DRUG DISTRIBUTION INTO SALIVA: THE IMPLICATION OF PROTEIN BINDING
Khalid Alkharfy, Tawfeeg Najjar, Sherif Saad

DMT-M-002
INVESTIGATION OF HUMAN PHASE II ENZYMES INVOLVED IN THE METABOLISM OF ROTIGOTINE
Käthe Becker, Susanne Bonsmann, Klaus Hansen, Ute Scharfenecker

DMT-M-003
GASTROPLUS PBPK SIMULATION OF SIMVASTATIN: UPTAKE TRANSPORT BY HEPATIC SEROSAL OATP, BILIARY EFFLUX TRANSPORT BY MUCOSAL PGP, AND METABOLISM BY CYP3A4 IN GUT AND LIVER.
Michael B. Bolger

DMT-M-004
PROTON-COUPLED BASOLATERAL DIPEPTIDE TRANSPORT IN A HUMAN INTESTINAL CELL LINE, CACO-2.
Birger Brodin

DMT-M-005
PHARMACOKINETIC INTERACTION BETWEEN THE BARK OF MAGNOLIAE OFFICINALIS AND METHOTREXATE IN RATS
Ying-Chen Chen, Shang-Yuan Tsai, Yu-Chi Hou, Pei-Dawn Lee Chao

DMT-M-006
EFFECT OF GER-GEN CHIN-LIEN TANG ON THE PHARMACOKINETICS OF VALPROIC ACID IN RATS
Lung-Yen Chen, Chung-Ping Yu, Su-Lan Hsiu, Yu-Chi Hou, Hsiu-Mei Chiang

DMT-M-007
INTERACTION CHARACTERISTICS OF FLAVONOIDS WITH MONOCARBOXYLATE TRANSPORTERS IN CACO-2 CELLS
Eun-Pa Cheon, Kisoo Seo, Hoo-Kyun Choi, Hyo-Kyung Han

DMT-M-008
INTERACTION BETWEEN A LEGUME FLOWER AND CARBAMAZEPINE IN RATS
Ying-chang Chi, Yu-Chi Hou, Pei-Dawn Lee Chao, Su-Lan Hsiu

DMT-M-009
DIFFERENT CYP3A4 ENZYME KINETICS OF MIDAZOLAM IN DIFFERENT MICROSOMAL PREPARATIONS
Hege Christensen, Lillian Wåge Postvoll, Liv Mathiesen, Siri Johannesen, Espen Molden

DMT-M-010
THE INFLUENCE OF EPINEPHRINE IN PH DEPENDENT AMPHETAMINE TRANSPORT *IN VITRO*
Andrew Crowe, Susanna Diep

DMT-M-011
A SINGLE DOSE OF RECOMBINANT ADENOVIRUS SIGNIFICANTLY ALTERS HEPATIC AND RENAL CYTOCHROME P450 EXPRESSION AND FUNCTION FOR 14 DAYS
Maria Croyle, Piyanuch Wonganan, Shellie Callahan

DMT-M-012
SATURABLE CARRIER-MEDIATED ABSORPTIVE TRANSPORT OF METFORMIN, A BIOPHARMACEUTICS DRUG DISPOSITION CLASSIFICATION SYSTEM (BDDCS) CLASS III COMPOUND
Joseph Custodio, Leslie Benet

DMT-M-013
PERMEABILITY STUDY OF ANDROGRAPHOLIDE THROUGH ARTIFICIAL MEMBRANE AND RAT SMALL INTESTINE
Supawadee Daodee, Wangboonskul Jinda, Kanokwan Jarukamjorn, Bungorn Sripanidkulchai

DMT-M-014
THE IMPACT OF ALOE VERA JUICE ON P-GLYCOPROTEIN EFFLUX OF DIGOXIN IN CACO-2 CELLS.
Ane Djuv, Odd Georg Nilsen

DMT-M-015
EFFECT OF HYPOURICEMIC AND HYPERURICEMIC DRUGS ON URATE TRANSPORT BY MULTIDRUG RESISTANCE PROTEIN (MRP) 4
Azza El-Sheikh, Jeroen J.M.W. Van den Heuvel, Jan B. Koenderink, Frans G.M. Russel

DMT-M-016
ASSESSMENTS OF THE INHIBITION OF P-GLYCOPROTEIN TRANSPORT IN CACO-2 CELLS BY WATER EXTRACT OF THE HERBAL REMEDY NATTO K2
Silje Engdal, Odd Georg Nilsen

DMT-M-017
IMPROVING ORAL ABSORPTION OF ANTIVIRAL DRUGS: TRANSPORT AND ACTIVATION OF A CYCLIC CIDOFOVIR PRODRUG
Ulrika Eriksson, Chester J. Provoda, John M. Hilfinger, Charles E. McKenna, Kyung-Dall Lee, Gordon L. Amidon

DMT-M-018
METABOLIC DIFFERENCES BETWEEN SPECIES
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附錄二

ORIGINAL RESEARCH ARTICLE

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Cardiovascular Events Associated with Long-Term Use of Celecoxib, Rofecoxib and Meloxicam in Taiwan

An Observational Study

Weng-Foung Huang,[1] *Fei-Yuan Hsiao*,[2] *Yi-Wen Tsai*,[1,3] *Yu-Wen Wen*[3] and *Yaw-Tang Shih*[3]

1 Institutes of Health and Welfare Policy, National Yang-Ming University, Taipei, Taiwan
2 Division of Health and Welfare Policy Management, Institutes of Public Health, National Yang-Ming University, Taipei, Taiwan
3 Division of Health Policy Research, National Health Research Institutes, Taipei, Taiwan

Abstract

Background: Using national data (2001–2003), this study explored the risk of acute myocardial infarction (AMI), angina, stroke and transient ischaemic attack (TIA) in long-term users of rofecoxib and celecoxib in Taiwan and compared this data with that for those using meloxicam.

Methods: Patients included in the study had used celecoxib, rofecoxib or meloxicam for at least 180 days. Data were taken from National Health Insurance database for the period from 2001 to 2003. Main outcome measurements were the occurrence of AMI, angina, stroke or TIA after the initiation of long-term continuous use of these drugs. Person-time exposures and hazard ratios (HRs) were calculated based on data from 9602 eligible patients.

Results: In patients without a history of a cardiovascular event within the year before drug treatment began, the overall rates of AMI, angina, stroke and TIA were 1.1%, 0.6%, 2.0% and 0.6%, respectively. In those with cardiovascular events in the year before treatment began, the overall rates of AMI, angina, stroke and TIA were 5.0%, 4.8%, 6.6% and 5.8%, respectively. Compared with meloxicam users, celecoxib users had lower HRs for the development of AMI (HR 0.78, 95% CI 0.63, 0.96) and stroke (HR 0.81, 95% CI 0.70, 0.93). Rofecoxib users were at no higher risk of cardiovascular events than those receiving meloxicam. Regardless of treatment, having had a cardiovascular event in the year before treatment began played a significant role in the development of the same cardiovascular event during the prescription period; the HRs associated with having had the same cardiovascular event in the past year, versus not having had such an event, were 3.02 (95% CI 1.44, 6.32) for AMI, 5.82 (95% CI 3.19, 10.63) for

angina, 2.44 (95% CI 1.79, 3.33) for stroke and 7.16 (95% CI 3.70, 13.87) for TIA.

Conclusions: Patients taking celecoxib had a lower risk of cardiovascular events than those taking meloxicam. Patients taking rofecoxib were not found to be at higher cardiovascular risk than those taking meloxicam. The most significant determinant of cardiovascular risk was a history of such cardiovascular disease in the year preceding treatment initiation. Patients with a history of other medical conditions also appeared to be at higher risk of adverse cardiovascular events.

Background

Selective cyclo-oxygenase (COX)-2 inhibitors ('coxibs') form a new category of NSAIDs that reduce the occurrence of adverse gastrointestinal tract effects.[1,2] However, recent results from several large trials of coxibs have suggested a possible relationship between these drugs, particularly rofecoxib, and increased rates of myocardial infarction. The withdrawal of rofecoxib (Vioxx®)[1] was initiated because of the increased cardiovascular risk to long-term users of this drug in the APPROVe (Adenomatous Polyp Prevention on VIOXX) study.[3-5] Most significantly, the US National Cancer Institute halted its APC (Adenoma Prevention with Celebrex) trial after the data safety monitoring board reported a 2.5-fold greater risk of acute myocardial infarction (AMI) and stroke in patients treated with celecoxib 400 mg/day.[6] Similar concern has been raised about the cardiovascular toxicity of other coxibs, such as valdecoxib.[3,6-11] For example, patients treated with valdecoxib after coronary artery bypass surgery have been reported to have higher rates of AMI, stroke and death than those treated with opioids for postoperative pain.[3] It was strongly recommended that prescription of valdecoxib be halted for the sake of public safety.[11]

Since then, the US FDA has asked Pfizer, Inc. to voluntarily suspend direct-to-consumer advertising of celecoxib (Celebrex®). They have further requested that the company indicate on package inserts that the FDA recommends that physicians consider alternative therapies.[12,13] Current reports on adverse reactions associated with the selective COX-2 inhibitors are based on results from controlled clinical trials,[1,2,4,5,9,14] but limited information are available on adverse reactions associated with the actual use of these drugs.

On 6 April 2005, the FDA's Decision Memo on NSAIDs indicated that the available data did not permit a rank ordering of selective COX-2 NSAIDs with regard to cardiovascular events, and that data from large, long-term, controlled clinical trials that have included comparisons of COX-2 selective and non-selective NSAIDs did not clearly demonstrate that the COX-2 selective agents conferred a greater risk of serious adverse cardiovascular events than non-selective NSAIDs. In one cumulated meta-analysis of 18 randomised controlled trials and 11 observational studies, there was little evidence to clarify the cardiovascular risk difference between selective COX-2 inhibitors and NSAIDs. The relative risk differed depending on the control group (placebo, non-naproxen NSAID or naproxen; $p = 0.41$) and the trial duration ($p = 0.82$).[15] The FDA further stated that the available data would be best interpreted as being consistent with a class effect of an increased risk of serious adverse cardiovascular events for COX-2 selective and non-selective

1 The use of trade names is for product identification purposes only and does not imply endorsement.

NSAIDs.[1,3] Recent literature has provided some evidence to support such statements.[1,11,16-18]

In Taiwan, two coxibs, rofecoxib and celecoxib, were on the market and covered by the National Health Insurance (NIH) Reimbursement System at the time that Merck Sharp & Dohme Inc. withdrew rofecoxib from the market (September 2004). Because both the coxibs and NSAIDs are widely used by patients with rheumatoid arthritis or osteoarthritis, diseases that are associated with older ages, it is important to clarify the association between COX-2 selective or non-selective NSAIDs and cardiovascular events, such as AMI. Reviewing data from the Bureau of National Health Insurance (BNHI) for the years 2001–2003, we examined the risk of AMI, angina, stroke or transient ischaemic attack (TIA) in long-term users of rofecoxib and celecoxib in Taiwan using a less-selective NSAID, meloxicam, as the comparator.

Methods

An observational study was performed to examine the occurrence of cardiovascular events in long-term users (over 180 days of cumulative use) of celecoxib, rofecoxib and meloxicam; to discover whether long-term use (>180 days) of the coxibs, celecoxib or rofecoxib, increases the risk of AMI, angina, stroke or TIA more than long-term use of meloxicam; and to identify which factors might be related to the risk of cardiovascular events in long-term users of coxibs.

Study Population

We obtained our data on users of celecoxib, rofecoxib and meloxicam in Taiwan from the BNHI, which provided coverage to nearly 99% of Taiwan's population during the study period. The BNHI's computerised files allowed for cohort identification, classification of cardiovascular risk factor status and endpoint ascertainment. Potential eligible patients included all enrollees with records indicating continuous use of celecoxib, rofecoxib or meloxicam for >180 days between 1 January 2001 and 31 December 2003. We excluded any patient who had used a combination of these drugs or had used these drugs in combination with any other NSAIDs. We also excluded any patient who stopped taking the drug they were receiving for more than 14 days before receiving another prescription. We further excluded any patient whose accumulated prescription duration was <180 days.

We chose users receiving >180 days of treatment as our study subjects based on our pilot analysis for this study. We focused on long-term users, as our study population was based on the results of the APPROVe (Adenomatous Polyp Prevention on VIOXX®) trial. According to the APPROVe trial, patients had a higher risk of having a cardiovascular event after 18 months (540 days) of treatment. In addition, the data of patients receiving <180 days of treatment were more likely confounded by drug switching and dose adjustment, and so they were not included in our final analysis.

Data Collection

We used NHI pharmacy claim data for the period between 1 January 2001 and 31 December 2003 to collect information on celecoxib, rofecoxib and meloxicam use. For each medicine prescribed in an outpatient visit, a pharmacy record was made that included the starting date (the date the first prescription was dispensed [t_0]), quantity, dose and duration of prescription. We defined the end date of prescription duration (t_1) as the prescription dispensing date plus the prescription duration. We created a prescription profile for each patient taking any of the three medicines for further screening purposes. We also created a medical history profile for each patient to retrieve clinical conditions related to this study that had existed before the initiation of treatment and to identify the initial occurrence of (hos-

pitalisation for) the cardiovascular events analysed in our study.

In our study, we did not differentiate between dosages of celecoxib because initial analysis indicated that 92% of celecoxib users were prescribed a daily dosage of 200mg (78.9%) or less (13.5%). Users of higher dosage rofecoxib (50mg) were excluded in this study because of a relatively small sample size (n = 108).

The outcome variables of interest in this study were the occurrence of (i.e. hospitalisation for) serious cardiovascular events after starting on one of the medicines. We classified these hospitalised study subjects on the basis of International Classification of Diseases (9th Edition) [ICD-9-CM] codes for AMI (410.xx and 411.xx), angina (413.xx and 414.xx), stroke (433.xx and 444.xx) or TIA (435.xx and 437.1).

The covariate variables included age, sex, accumulated prescription duration and pre-existing (in the previous 1 year) medical conditions, as indicated by ICD-9-CM codes, of hypertension (401.xx–405.xx), hyperlipidaemia (272.4), diabetes mellitus (250.xx), heart failure (428.xx), and chronic kidney disease (580.xx-587.xx).

Statistical Analysis

We used descriptive statistics to compare the age, sex, prescription duration, occurrence of cardiovascular events in the year prior to treatment initiation, and the medical conditions of patients using the different drugs (celecoxib, rofecoxib and meloxicam).

A Cox proportional hazards model was used to evaluate the association of long-term use of selective COX-2 inhibitors with the subsequent risks of occurrence or recurrence of AMI, angina, stroke or TIA. A Cox proportional hazards model was used to compare the associations of the long-term use of selective COX-2 inhibitors and meloxicam with the subsequent risks of occurance or recurrence of AMI, angina, stroke or TIA. The entry day was the date of the first outpatient visit at which one of the three medications was prescribed. Follow-up time for each cardiovascular event extended until the earliest of the occurrence of hospitalisation for the specific cardiovascular event or until the end of the study period for those patients who did not have any cardiovascular events. The survival time of those patients did not have any cardiovascular event (outcome) and those who died during the study period were censored at the end of the study period and the day of death, respectively. Median time-to-onset among each subgroup is presented in table I.

A Cox proportional hazards model was performed using the package 'coxph' from S-plus Version 7.0.3. The assumption of the Cox proportional hazards model was checked and this check indicated that proportional hazards were a reasonable assumption (all p-values were >0.05). Residual analysis showed that the residuals were distributed around zero between −3 and 3 with no particular pattern, indicating that the model was a reasonable fit.

Results

Patient Characteristics

A total of 9602 patients were identified as receiving long-term treatment with celecoxib (n = 3762, 39.2%), rofecoxib (n = 1550, 16.1%) or meloxicam (n = 4290, 44.7%), with a total of 10 905 person-years of follow-up (table II). Nearly 75% of the patients were aged ≥64 years. The average accumulated duration of prescription over 3 years was 414.52 days (SD = 218.01). Meloxicam was taken for a longer duration than the other two drugs: 471.27 days (SD = 257.51) compared with 382.52 days (SD = 175.93) for celecoxib and 338.8 days (SD = 142.28) for rofecoxib ($p < 0.001$). Meloxicam was taken continuously for over 540 days by 33.64% of users.

Table I. Median time-to-onset (days) of cardiovascular events in continuous users of celecoxib, rofecoxib and meloxicam in Taiwan, 2001–2003

Subgroup	AMI	Angina	Stroke	TIA
Drug				
Meloxicam	392	393	394	393.5
Celecoxib	393	393.5	388.5	393
Rofecoxib	388	387	385	387
Age (y)				
≤44	380	402	393	413
45–54	385	392	385	399
55–64	392	405	382	385
>64	393	391	392	392
Sex				
Female	394	395	392	392
Male	388	388	389	392
Prescription duration (d)				
180–270	386	378	391	378
271–365	395.5	392	378	386.5
366–455	385	391	403.5	402.5
456–540	392	393	390	409
>540	403	418	395	406
Cardiovascular event in the year preceding treatment initiation				
Yes	358.5	392	392	379
No	392	402	402	392
Pre-existing medical condition				
Hypertension				
yes	389	391	391	385
no	394	394	392	399
Hyperlipidaemia				
yes	400	393	387	374
no	392	392	392	393
Diabetes mellitus				
yes	382	386	383	392
no	393	393	393	392
Heart failure				
yes	413	396	406	368
no	392	392	392	393
Chronic renal disease				
yes	372	375	381	392
no	393	393	392	399

AMI = acute myocardial infarction; **TIA** = transient ischaemic heart attack.

Of the 9602 patients, 180 (1.87%) had medical histories of AMI, 316 (3.29%) had a history of angina, 849 (8.84%) had a history of stroke and 191 (1.99%) had a history of TIA within the year preceding treatment initiation. Compared to meloxicam users, a higher proportion of COX-2 inhibitor users (particularly rofecoxib users) had medical histories of adverse cardiovascular events before they started taking these medications regularly ($p = 0.013$). Hypertension was present in 45.63% of the study popu-

Table II. Demographic information[a] of continuous users of celecoxib, rofecoxib and meloxicam in Taiwan, 2001–2003

Subgroup	Total (n = 9602)	Celecoxib (n = 3762)	Rofecoxib (n = 1550)	Meloxicam (n = 4290)	p-Value (Chi-squared)
Age (y)					0.348
≤44	619 (6.45)	241 (6.41)	88 (5.68)	290 (6.76)	
45–54	710 (7.39)	274 (7.28)	101 (6.52)	335 (7.81)	
55–64	1079 (11.24)	404 (10.74)	170 (10.97)	505 (11.77)	
>64	7194 (74.92)	2843 (75.57)	1191 (76.84)	3160 (73.66)	
Mean age in years (SD)	69.84 (14.42)	70.5 (14.15)	70.7 (13.96)	69.53 (14.66)	
Sex					0.191
Female	5644 (58.78)	2240 (59.54)	881 (56.84)	2523 (58.81)	
Male	3958 (41.22)	1522 (40.46)	669 (43.16)	1767 (41.19)	
Prescription duration (d)					<0.001
180–270	3223 (33.57)	1320 (35.09)	651 (42.00)	1252 (29.18)	
271–365	1996 (20.79)	824 (21.90)	387 (24.97)	785 (18.30)	
366–455	1187 (12.36)	498 (13.24)	211 (13.61)	478 (11.14)	
456–540	841 (8.76)	377 (10.02)	132 (8.52)	332 (7.74)	
>540	2355 (24.53)	743 (19.75)	169 (10.90)	1443 (33.64)	
Mean prescription duration in days (SD)	414.52 (218.01)	382.52 (175.93)	338.8 (142.28)	471.27 (257.51)	
Cardiovascular event within the year preceding treatment initiation					
Acute myocardial infarction	180 (1.87)	77 (2.05)	40 (2.58)	63 (1.47)	0.013
Angina	316 (3.29)	128 (3.40)	88 (5.68)	100 (2.33)	<0.001
Stroke	849 (8.84)	356 (9.46)	160 (10.32)	333 (7.76)	<0.001
Transient ischaemic attack	191 (1.99)	88 (2.34)	43 (2.77)	60 (1.40)	<0.001
Pre-existing medical condition					
Hypertension	4381 (45.63)	1774 (47.16)	828 (53.42)	1779 (41.47)	<0.001
Hyperlipidaemia	615 (6.40)	264 (7.02)	129 (8.32)	222 (5.17)	<0.001
Diabetes mellitus	1921 (20.01)	750 (19.94)	391 (25.23)	780 (18.18)	<0.001
Heart failure	511 (5.32)	231 (6.14)	92 (5.94)	188 (4.38)	<0.001
Chronic renal disease	635 (6.61)	266 (7.07)	99 (6.39)	270 (6.29)	0.348

a Data presented as number of patients (percentage) unless otherwise stated.

lation, 6.40% had hyperlipidaemia, 20.01% had diabetes mellitus, 5.32% had heart failure and 6.61% had chronic renal disease. Histories of hypertension, hyperlipidaemia and diabetes mellitus were all more frequent in rofecoxib users compared with the other two study groups (all $p < 0.001$).

Occurrence and Median Time-To-Onset of Cardiovascular Events During Prescription Duration

During the study period, 113 individuals had an AMI, 67 developed angina, 233 had a stroke and 68 experienced a TIA. Table III stratifies the occurrence of cardiovascular events with each drug according to the occurrence of each cardiovascular event in the year preceding treatment initiation. This shows that, during the study period, the prevalence of AMI for those with a medical history of the same disease was 5%, while only 1.10% of those without medical histories of AMI experienced this cardiovascular event. In those without medical histories of AMI, the rate of occurrence of AMI during the study period was highest among meloxicam users (1.37%), followed by celecoxib users (0.92%) and rofecoxib users (0.79%). The same trend was observed in meloxicam users for other cardiovascular events, however, rofecoxib users had higher rates of occurrence for angina, stroke and TIA than celecoxib users.

For patients with medical histories of AMI, recurrence of AMI occurred in 10% of rofecoxib users, followed by 3.90% of celecoxib recipients and 3.17% of meloxicam recipients. A similar trend was observed for angina. Concerning the cardiovascular event of stroke, meloxicam users had the highest recurrence rate (7.21%), followed by celecoxib users (6.46%) and rofecoxib users (5.63%). Rofecoxib users with prior medical histories of TIA had the highest rate of recurrence of TIA (6.98%), followed by meloxicam (6.67%) and celecoxib (4.55%) users (table III).

Table I shows the median time-to-onset of cardiovascular events according to sex, age, prescription duration, medical history of cardiovascular events, other pre-existing medical conditions and drug used. Time-to-onset of AMI, angina and TIA was longer in users of meloxicam and celecoxib than it was in users of rofecoxib. Time-to-onset of stroke was longer in users of meloxicam than it was for users of celecoxib and rofecoxib.

Survival Analysis on Cardiovascular Events

Table IV shows the results of the survival analysis for each cardiovascular event adjusted for sex, age, prescription duration, medical history of cardiovascular events and other pre-existing medical conditions. Compared to meloxicam users, celecoxib users had a lower risk of AMI (adjusted hazard ratio [HR] 0.78, 95% CI 0.63, 0.96). Having a medical history of AMI was significantly associated with AMI during the study period (HR 3.02, 95% CI 1.44, 6.32). Patients with medical histories of diabetes and chronic renal disease also had higher risks of developing AMI (HR 1.60, 95% CI 1.06, 2.41 and HR 1.81, 95% CI 1.05, 3.12, respectively).

The risk of angina during the prescription period is shown in table IV. Having a medical history of angina was significantly associated with the occurrence of angina during the study period (HR 5.82, 95% CI 3.19, 10.63). Patients with a medical history of heart failure had a higher risk of developing angina (HR 1.98, 95% CI 1.00, 3.91) than those who had not had heart failure.

As for the risk of stroke during prescription period, celecoxib users had a lower risk of stroke (HR 0.81, 95% CI 0.70, 0.93) than meloxicam users. Having a medical history of stroke was also significantly associated with the occurrence of stroke during the study period (HR 2.44, 95% CI 1.79, 3.33). Patients with a medical history of diabetes had a higher risk of developing stroke during prescription

Table III. Cardiovascular events during prescription period among users of celecoxib, rofecoxib and meloxicam users with/without such events in the year preceding treatment initiation; Taiwan, 2001–2003

Event	Celecoxib		Rofecoxib		Meloxicam		Total	
	with a history	without a history	with a history	without a history	with a history	without a history	with a history	without a history
AMI								
Prescription duration[a]	381.36 (173.65)	383.56 (176.00)	304.00 (130.88)	339.72 (142.50)	420.92 (237.89)	472.02 (257.74)	378.02 (194.97)	416.22 (218.90)
Occurrence during the prescription period[b]	3/77 (3.90)	34/3685 (0.92)	4/40 (10.00)	12/1510 (0.79)	2/63 (3.17)	58/4227 (1.37)	9/180 (5.00)	104/9422 (1.10)
Angina								
Prescription duration[a]	371.83 (158.22)	383.93 (176.53)	344.92 (143.26)	338.43 (142.27)	423.45 (240.33)	472.41 (257.82)	380.67 (186.77)	416.69 (219.44)
Occurrence during the prescription period[b]	6/128 (4.69)	16/3634 (0.44)	5/88 (5.68)	8/1462 (0.55)	4/100 (4.00)	28/4190 (0.67)	15/316 (4.75)	52/9286 (0.56)
Stroke								
Prescription duration[a]	346.39 (151.03)	387.40 (177.91)	324.09 (132.90)	340.49 (143.27)	418.49 (233.87)	475.71 (258.93)	370.47 (189.29)	419.87 (220.68)
Occurrence during the prescription period[b]	23/356 (6.46)	55/3406 (1.61)	9/160 (5.63)	26/1390 (1.87)	24/333 (7.21)	96/3957 (2.43)	56/849 (6.60)	177/8753 (2.02)
TIA								
Prescription duration[a]	351.91 (147.52)	384.27 (176.50)	347.33 (152.46)	338.56 (142.03)	321.25 (145.81)	473.40 (258.13)	341.25 (147.96)	417.01 (219.47)
Occurrence during the prescription period[b]	4/88 (4.55)	18/3674 (0.49)	3/43 (6.98)	9/1507 (0.60)	4/60 (6.67)	30/4230 (0.71)	11/191 (5.76)	57/9411 (0.61)

a Data in days [mean (SD)]

b Data in number of patients/total number of patients (%).

AMI = acute myocardial infarction; **TIA** = transient ischaemic attack.

Table IV. Risk of cardiovascular events in celecoxib, rofecoxib, and meloxicam users in Taiwan, 2001–2003

Covariate	Acute myocardial infarction		Angina		Stroke		Transient ischaemic attack	
	HR (95% CI)	p-value	HR (95% CI)	p-value	HR (95% CI)	p-value	HR (95% CI)	p-value
Sex								
female	1.00		1.00		1.00		1.00	
male	1.16 (0.96, 1.39)	0.13	0.89 (0.69, 1.14)	0.36	1.06 (0.93, 1.21)	0.35	1.03 (0.81, 1.30)	0.84
Drug								
meloxicam	1.00		1.00		1.00		1.00	
celecoxib	0.78 (0.63, 0.96)	0.02	0.84 (0.63, 1.10)	0.20	0.81 (0.70, 0.93)	0.00	0.79 (0.60, 1.03)	0.08
rofecoxib	0.91 (0.76, 1.09)	0.30	1.01 (0.82, 1.24)	0.91	0.93 (0.83, 1.05)	0.27	0.98 (0.80, 1.21)	0.86
Age (y)	1.04 (1.02, 1.06)	0.00	1.03 (1.00, 1.05)	0.02	1.05 (1.04, 1.06)	0.00	1.04 (1.01, 1.06)	0.00
Prescription duration (d)	1.00 (1.00, 1.00)	0.26	1.00 (1.00, 1.00)	0.83	1.00 (1.00, 1.00)	0.05	1.00 (1.00, 1.00)	0.10
Cardiovascular event of same type in the year preceding treatment initiation								
no	1.00		1.00		1.00		1.00	
yes	3.02 (1.44, 6.32)	0.00	5.82 (3.19, 10.63)	0.00	2.44 (1.79, 3.33)	0.00	7.16 (3.70, 13.87)	0.00*
Prior medical condition								
Hypertension								
no	1.00		1.00		1.00		1.00	
yes	1.25 (0.85, 1.85)	0.26	1.59 (0.92, 2.73)	0.10	1.09 (0.82, 1.43)	0.56	1.76 (1.04, 2.96)	0.03
Hyperlipidaemia								
no	1.00		1.00		1.00			
yes	0.86 (0.39, 1.86)	0.69	1.55 (0.73, 3.31)	0.25	0.46 (0.22, 0.93)	0.03	NA	
Diabetes mellitus								
no	1.00		1.00		1.00		1.00	
yes	1.60 (1.06, 2.41)	0.02	1.17 (0.68, 2.02)	0.58	1.79 (1.35, 2.37)	0.00	1.23 (0.71, 2.11)	0.46
Heart failure								
no	1.00		1.00		1.00		1.00	
yes	1.69 (0.94, 3.02)	0.07	1.98 (1.00, 3.91)	0.04	1.37 (0.89, 2.11)	0.15	1.06 (0.42, 2.67)	0.90
Chronic renal disease								
no	1.00		1.00		1.00		1.00	
yes	1.81 (1.05, 3.12)	0.03	1.63 (0.79, 3.36)	0.19	1.37 (0.90, 2.08)	0.15	0.67 (0.24, 1.87)	0.45

HR = hazard ratio; **NA** = not applicable.

period (HR 1.79, 95% CI 1.35, 2.37) than those who had not had this disease.

Similarly, having a medical history of TIA was significantly associated with the occurrence of TIA during the study period (HR 7.16, 95% CI 3.70, 13.87). Patients with a medical history of hypertension had a higher risk of developing TIA during the prescription period than those who had no history of hypertension (HR 1.76, 95% CI 1.04, 2.96).

Discussion

The possible association of coxibs with cardiovascular adverse events has evolved into an important drug safety issue. When the pharmacology of the COX enzymes is considered it is not surprising to see that the thrombosis effect (COX-1 pharmacology), blocked by non-selective NSAIDs, is overexpressed in the selective COX-2 inhibitors model. The beneficial effect of both non-selective NSAIDs and selective COX-2 inhibitors on inflammation comes through inhibition of the COX-2 pathway. However, COX-1 is responsible for the thrombosis in the human body. Thus, non-selective NSAIDs, such as aspirin (which blocks COX-1 pathway), might provide an antiplatelet effect and help prevent cardiovascular disease. Without NSAID blockade of the COX-1 pathway, it would also be reasonable to suspect increased cardiovascular risk in users of COX-2 inhibitors compared with users of non-selective NSAIDs.[19] A question exists as to whether there is a significant 'class effect' produced by coxibs. Previous reports on the relationship between coxibs and cardiovascular disease were only obtained from controlled clinical trials. Clinical trials are considered to generate the most accurate results, yet they tend to be time-consuming to perform, with limitations provided by inclusion and exclusion criteria. The FDA's Decision Memo on 6 April 2005 provides an updated benchmarking of NSAID safety, both for coxibs and non-selective NSAIDs.[1,3]

Studies such as this, which are based on population-based data on the utilisation of coxibs, provide new information on selective COX-2 inhibitor safety to supplement the limitations in the data provided by clinical trials. As far as we know, no head-to-head comparisons of COX-2 inhibitors and NSAIDs in randomised trials are available to enable determination of the relative risks of cardiovascular events. Also, major trials have excluded patients with coronary heart disease and only a few such trials have been designed to measure cardiovascular events after patients have received selective COX-2 inhibitors and NSAIDs. We used 3 years of national data (2001–2003) as a resource to construct a large national cohort and provide longitudinal information on users of celecoxib, rofecoxib and meloxicam. In addition, since all information, including pharmacy records, was recorded on the computer, there was not the kind of recall bias that would occur with a survey-based study design. The most important risk factors for cardiovascular events in our study were the previous occurrence of a cardiovascular event or a pre-existing medical condition within the year before treatment with these drugs began.

This study has some design limitations. First, because we defined long-term users as those with >180 days of cumulative use of study medications, termination of drug prescription due to cardiovascular adverse events prior to this was not covered. Since it has been found that the time-to-onset of cardiovascular events varies from 6 weeks (42 days) to 56 weeks (392 days) from the initiation of treatment with coxibs,[15] future studies using a different definition of long-term users could be useful. Second, we selected users of meloxicam as our control group because the medication was widely prescribed in Taiwan and the BNHI was interested in it; cardiovascular risk comparisons between coxibs and other non-selective NSAIDs might also be clinically relevant. A truly non-selective NSAID, instead of a less selective COX-2 inhibitor like meloxicam,

might be a better comparator. Third, although we adjusted for a wide range of potential cardiovascular risk factors, it is difficult to control the potential confounding factor of patients taking non-prescribed NSAID medication or aspirin during the study period. Nor did we have any information on patient compliance. We also did not have information on the patients' smoking histories and family histories of cardiovascular disease. Fourth, because of data limitation (2001–2003, NHI database), only cardiovascular events that occurred within 1 year prior to treatment initiation were screened; therefore, some information bias could exist in our study. Finally, because we did not link to the National Mortality File databases, we did not know if fatal cardiovascular events occurred. Nonetheless, the results from our study offer unique insight into the real-life risks of the long-term usage of coxibs.

We found no significant difference in the rates of adverse cardiovascular events between the two coxibs, celecoxib and rofecoxib. Prior cardiovascular history was the most significant determinant of such risks. Patients with a history of other medical conditions were also found to be subject to a higher risk of cardiovascular events. Several controversies about the cardiovascular safety of celecoxib and other conventional NSAIDs still remain. The potential beneficial effects of celecoxib and its protective effects on endothelial function and coronary blood flow have been reported.[20]

Though package inserts for coxibs include a warning for patients with a cardiovascular event history, physicians may not have sufficient information to alert their patients with osteoarthritis or rheumatoid arthritis, who may consider taking coxibs, to the risks and benefits of their use. In addition, coxibs also present a costly lesson for regulatory agencies when they compare their possible benefits of reducing existing manageable adverse reactions with the possible risks of increasing unexpected adverse events.[21,22] Although an earlier FDA panel meeting raised concerns regarding coxib class effects, the same panel also voted to allow the return of rofecoxib to the market with a restrictive black box warning.[22] Recent reports tend to support the concept of class effects on cardiovascular events for both coxibs and non-selective NSAIDs, although the risks vary depending on study populations and the individual drugs.[17-19,21,23] The cardiovascular effects of non-selective NSAIDs pose similar cardiovascular concerns to those of coxibs. Our observational study seems to support, although not conclusively, a class-effect regarding the association of coxibs with adverse cardiovascular events. Our control group, who received the less-selective NSAID, meloxicam, had no less risk for adverse cardiovascular events than the groups using coxibs. Consequently, the potential risks from use of all coxibs and non-selective NSAIDs need continued exploration.

Conclusion

There is no significant difference between celecoxib and rofecoxib with regard to their association with adverse cardiovascular events. Celecoxib was associated with a lower risk of AMI and stroke than meloxicam. In contrast to previous reports, we found rofecoxib users to be at no higher risk of cardiovascular events than those receiving meloxicam. Instead, we found a close enough association between meloxicam and a higher risk of cardiovascular events to warrant caution regarding the safety of non-selective NSAIDs. A prior history of cardiovascular disease was the most significant determinant of such risks. Patients with a history of other medical conditions also appeared to have a higher risk of cardiovascular events when taking coxibs.

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Correspondence and offprints: Dr *Weng-Foung Huang*, Li-Nong Street Section 2, Institute of Health and Welfare Policy, National Yang Ming University, Shih-Pai, Taipei, 155, Taiwan.
E-mail: huang@ym.edu.tw