# 行政院所屬各機關因公出國人員出國報告

（出國類別：參加國際會議）

# 赴捷克參加「藥品資訊協會第十六屆歐洲年會（The 16th DIA EuroMeeting）」

# 出國報告


服 務 機 關：行政院衛生署中醫藥委員會

出 國 人　職　　稱：薦任組員

姓　　名：鍾慧茹


出國地區：捷克・布拉格

出國期間：民國九十三年三月八日至三月十五日

報告日期：民國九十三年四月二十九日

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# 公務出國報告提要

出國報告名稱：　　頁數：27 含附件：☑是□否

赴捷克參加「藥品資訊協會第十六屆歐洲年會(The 16th DIA EuroMeeting)」

出國計畫主辦機關／聯絡人／電話

中醫藥委員會　江盈盈　02-25872828 ext.267

出國人員姓名／服務機關／單位／職稱／電話

鍾慧茹　中醫藥委員會　科技政策小組　薦任組員

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出國類別：□1 考察□2 進修□3 研究□4 實習☑5 其他

出國期間：民國九十三年三月八日至十五日　出國地區：捷克

報告日期：民國九十三年四月二十九日

分類號／目：J1／中醫　J0／綜合（醫藥類）

關鍵詞：藥品、植物藥、法規、臨床試驗、歐盟、DIA

內容摘要：

建立醫藥衛生產業發展優勢環境，提昇生物技術產業競爭力，為本署（會）主要施政項目。依據行政院核定之「加強生物產業推動方案」及「中草藥產業技術發展五年計畫」，本署（會）於部會分工中之任務為「臨床試驗的推動與相關法規的建立」。為健全我國中草藥臨床試驗及法規環境，促進新藥研發及產業升級，本署中醫藥委員會身為全國中醫藥最高行政主管機關，有必要了解在國際化的趨勢下，如何影響新醫療產品之研發、申請與上市之經營操作方式，俾推動重要政策時將國際發展趨勢融入，爰派員參加本月 10 日至 12 日於捷克

布拉格舉行之「藥品資訊協會第十六屆歐洲年會 The 16th DIA EuroMeeting」。本次會議參與者多達二千餘人，主要參與國家為西歐、北歐及中東歐各國，以及美國、加拿大、澳洲、日本、新加坡、中國大陸及亞洲新興國家，會議內容涵蓋新藥與新技術之發表、製程品質的管控、以及日漸重要的臨床前研究議題、國際面及歐盟的相關法規議題（尤其是植物藥的部分）、臨床試驗及專案管理、統計與資料處理分析、藥物副作用監測、公共衛生、民眾獲得醫療之普及性，以及當易受傷害的特殊族群成為臨床研究對象時之倫理議題等。本會除於會中與多位歐盟衛生單位主管交流，並邀請其日後來訪及給予經驗分享指導外，亦將於會後充分彙整資訊，於爾後修訂法規及推動相關重要政策時，將國際發展趨勢融入，以與國際同步。

本文電子檔已上傳至出國報告資訊網(http://report.gsn.gov.tw)

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# 摘要

建立醫藥衛生產業發展優勢環境，提昇生物技術產業競爭力，為本署（會）主要施政項目。依據行政院核定之「加強生物產業推動方案」及「中草藥產業技術發展五年計畫」，本署（會）於部會分工中之任務為「臨床試驗的推動與相關法規的建立」。為健全我國中草藥臨床試驗及法規環境，促進新藥研發及產業升級，本署中醫藥委員會身為全國中醫藥最高行政主管機關，有必要了解在國際化的趨勢下，如何影響新醫療產品之研發、申請與上市之經營操作方式，俾推動重要政策時將國際發展趨勢融入，爰派員參加本月 10 日至 12 日於捷克布拉格舉行之「藥品資訊協會第十六屆歐洲年會 The 16th DIA EuroMeeting」。本次會議參與者多達二千餘人，主要參與國家為西歐、北歐及中東歐各國，以及美國、加拿大、澳洲、日本、新加坡、中國大陸及亞洲新興國家，會議內容涵蓋新藥與新技術之發表、製程品質的管控、以及日漸重要的臨床前研究議題、國際面及歐盟的相關法規議題（尤其是植物藥的部分）、臨床試驗及專案管理、統計與資料處理分析、藥物副作用監測、公共衛生、民眾獲得醫療之普及性，以及當易受傷害的特殊族群成為臨床研究對象時之倫理議題等。本會除於會中與多位歐盟衛生單位主管交流，並邀請其日後來訪及給予經驗分享指導外，亦將於會後充分彙整資訊，於爾後修訂法規及推動相關重要政策時，將國際發展趨勢融入，以與國際同步。

關鍵詞：藥品、植物藥、法規、臨床試驗、歐盟、DIA

## 壹、 目的

行政院衛生署中醫藥委員會為全國中醫及中藥最高行政主管機關，為健全國內中藥臨床試驗及法規環境，促進新藥研發及產業升級，有必要了解在國際化的趨勢下，如何影響新醫療產品之研發、申請與上市之經營操作方式，期在推動相關重要政策時，能將國際發展趨勢融入，爰派員參加本次會議。

## 貳、 過程

### 一、行程

本次代表行政院衛生署中醫藥委員會參加，為求全程參與，報告人於三月八日傍晚啟程，經香港及巴黎轉機至布拉格。估算飛行及轉機等候時間共約二十餘小時，因時差關係，抵達布拉格為當地時間三月九日中午，隨即至飯店 check-in。

因本次會議自會前一日，即三月九日下午二時起就開始報到手續，故用過午餐後，即搭乘地鐵前往布拉格國際會議中心報到，並參觀會場相關展覽攤位。

本次會議的主題為「Expanding Horizons – Hopes and Challenges」，其主要宗旨是要提供機會給每位參與者更進一步了解在國際化的趨勢下（尤其是歐盟的擴展），如何影響新醫療產品之研發、申請與上市之經營操作方式。大會於三月十日下午二時正式開幕，由 DIA 總會會長 Dr. Eleanor Perfetto、DIA 歐洲分部執行長 Dr. Wayne Nitchuk、布拉格市長等分別給予開幕演說，之後進入 plenary session，讓與會者與歐盟法規單位主管直接互動並發問問題。參與該 Q. & A. 時段的歐盟衛生官員包括 Dr. Philippe Brunet（from European Commission, Belgium）、Dr. Thomas Lonngren（from EMEA, U.K.）、Dr. Daniel Brasseur（from CPMP, Belgium）、Dr. Milan Smid（from State

Institute for Drug Control, Czech)，以及 Dr. Josef Torrent-Farnell (from COMP, Spain)。由於今年預計會有十五個中東歐國家再加入歐盟，因此二十多個不同語言國家間衛生主管單位之協商，以及如何達成共識，將是 2004 年歐盟所面臨的最大挑戰。而對於這些新加入歐盟之國家，如何將其醫藥品審查水準與西歐國家拉平(未來這些中東歐國家與其他西歐國家在歐盟的參與權及投票權都是相同的)，並給予其相關衛生主管官員教育訓練，在此廣泛地被討論。此外，歐盟地區的藥物不良反應監測系統及臨床試驗的申請也是熱烈地討論的重點。Plenary Session 之後為 DIA 傑出事業與傑出服務獎頒獎典禮，受獎者皆為過去對 DIA 有重大貢獻之政府法規單位官員或業界精英。最後在大會精心安排下，整個開幕式於精采的布拉格黑光劇表演中落幕。當晚大會並安排了豐盛的百匯晚餐，提供所有與會者一個自由交談、與他人建立互動的最佳社交場合。

三月十一至十二日之大會議程則分為十五個不同主題之講座同步進行，內容包括新藥與新技術之發表、製程品質的管控、以及日漸重要的臨床前研究議題、國際面及歐盟的相關法規議題(尤其是植物藥的部分)、臨床試驗及專案管理、統計與資料處理分析、藥物副作用監測、公共衛生、民眾獲得醫療之普及性，以及當易受傷害的特殊族群成為臨床研究對象時之倫理議題等。整個 EuroMeeting 於三月十二日下午五時三十分閉幕，報告人全程參加大會議程及所有 social event。

二、DIA 簡介

DIA 全名為 Drug Information Association (藥品資訊協會)，成立於 1964 年，為一科學性的協會團體，致力於改善全世界的健康照護環境，提供最新的醫藥品發展訊息，推展創新的、安全的、有效的治療，解決罕見疾病患者的痛苦，並使人類的生活更加美好。其參與之

會員來自全球許多國家之醫界、製藥界、研發界、學界，以及政府機構。目前該組織在全球已有超過 30,000 名會員，而其歷年在美國 FDA 或歐盟 EMEA 協助下辦理的臨床試驗及藥物開發專案管理課程，內容均十分豐富，培訓的人才更是不計其數，為一相當有影響力之國際團體組織。

DIA 的管理總部（administrative headquarters）設於美國賓州 Horsham，另外在瑞士 Basel 及日本東京亦設有區域辦公室(regional office)。身為一個非營利性且財源自給自足之獨立組織，DIA 藉由每年舉辦多場不同主題的國際研討會，提供會員一個中立的論壇以交換醫藥界最新資訊、科學觀點，及與製藥業息息相關的醫藥、技術、法規議題。目前 DIA 更積極擴展其活動觸角至東歐、太平洋地區、中南美洲及中東地區，以更貼切地服務這些地區會員們的需求。

三、會議內容節錄

2004 年 3 月 10 日至 3 月 12 日於捷克布拉格舉行之「第十六屆藥品資訊協會歐洲年會」的主題為「擴展疆界－希望與挑戰」(Expanding Horizons – Hopes and Challenges)，其主要宗旨是要提供機會給每位參與者更進一步了解在國際化的趨勢下，如何影響新醫療產品之研發、申請與上市之經營操作方式。本次會議參與者達二千餘人，主要來自歐洲國家，其次為美國、加拿大、澳洲、日本、新加坡、中國大陸及亞洲新興國家。本次會議內容涵蓋新藥與新技術之發表、製程品質的管控、以及日漸重要的臨床前研究論題、國際面及歐盟的相關法規議題、臨床試驗與治療學領域、統計與資料處理分析、藥物副作用監測、流行病學、專案管理及委外尋求協助( project management and outsourcing)、公共衛生、民眾獲得醫療之普及性、孤兒藥，以及當易受傷害的特殊族群成為臨床研究對象時之倫理議題等。

上述課程分成 15 tracks 於同一時段分別於不同場地舉行，對獨自

參加者而言，單憑一己之力是無法同步參加上述全部課程的，故報告人選擇了與本會業務執行面較直接相關之課程場次參加，即 Track 14「OTC/SM and Herbal Products」與 Track2「Clinical Trials and Therapeutic Areas」，其內容主要討論歐盟對於非處方藥及植物藥產品未來的立法管理架構，以及藥品優良臨床試驗規範之查核（GCP inspection）在美國及歐盟執行的情形及其危機管理。節錄重要內容如下：

（1）歐盟對於植物藥產品未來的管理立法架構

**EMEA 簡介：**

EMEA (The European Agency for the Evaluation of Medicinal Products) 於 1995 年 1 月在倫敦成立，其主要任務是透過對人用及動物用醫藥品的審核與把關，來維護及促進大眾與動物的健康。該機構是以一個網絡的方式運作，將各會員國的科學資源集合在一起，以確保歐洲醫藥產品受到最高等級的審核與監督。EMEA 在廣泛的醫藥法規議題方面，有許多合作密切的國際夥伴。而超過 3000 名專家（來自歐洲各地區）所組成的網絡，支援 EMEA 及其所屬委員會的科學性工作。

EMEA 每年度的經費預算及工作計畫需經由 Management Board 通過，而 Management Board 是各個會員國各別推派二名代表（由 European Parliament and European Commission 中推派）所組成。

在醫藥品的審核方面，EMEA 有三個委員會可提供科學性的意見，包括 Committee for Proprietary Medicinal Products（簡稱 CPMP，其負責人用藥品的部分）、 Committee for Veterinary Medicinal Products (簡稱 CVMP，其負責動物用藥品的部分)，以及 Committee for Orphan Medicinal Products（簡稱 COMP；其

負責治療罕見疾病的孤兒藥部分)。其中 CPMP 及 CVMP 是由會員國各推派二名代表所組成；而 COMP 則是由各會員國各自推派一名代表，再加上來自各個病患族群的代表所組成。

歐盟藥物核准的途徑：

歐盟對藥物核准，提供以下兩種途徑，而 EMEA 在兩者皆扮演一席之地：

1. Centralized Procedure（中央認證途徑）：

『藉由生物科技而來的藥品』強制規定必須經由中央認證途徑才准予上市；而對於研發的新藥，則可應藥廠公司的要求來審核。經此途徑的申請案件將直接送至 EMEA，由 EMEA 在 210 天內達成科學評估的結論，而 EMEA 科學委員會的意見將送交至歐洲議會，藉由歐洲議會中各會員國代表所組成之常設委員會的協助下，正式通過其決議，並轉化成單一市場的許可認證，適用於全歐盟範圍。

2. Non-centralized Procedure（相互認證途徑）：

主要應用於一般或傳統藥品，並根據歐盟各國間相互認證的原則來進行。此途徑提供申請者，只要於一個會員國許可上市，便可以將市場許可範圍延伸到一至多個會員國。倘若第一個會員國的核准不被其他會員國承認，有爭議的項目將會送至 EMEA 進行裁決，而 EMEA 科學委員會提供的意見將送交至歐洲議會，藉由歐洲議會中各會員國代表所組成之常設委員會的協助下，正式通過其決議。

為因應植物藥產品的審查及管理，EMEA 於 2002 年在 CPMP 之下設置了「Herbal Medicinal Products Working Party」，到了 2004 年更成立了「Committee for Herbal Medicinal Products」，這個委員會提供了一個新的科學專家顧問群來評估藥用植物，以及提供

植物藥產品核准之指引原則。在過去 CPMP 發現要將 Directive 65/65 應用在植物藥產品上是不可能的，主要是基於「efficacy」的理由，而在這方面也一直都沒有其他的立法在推動。而如今「Committee for Herbal Medicinal Products」的成立，以及「Directive on traditional herbal medicinal products」的採用，應該可以解決這部分的問題。

**Directive on traditional herbal medicinal products：**

為改善植物藥產品法規管理架構，歐盟於 2002 年首次提出「Directive on traditional herbal medicinal products」草案，經過二年來不斷地協商修正，預期將於 2004 年的歐盟部長會議中通過。有關該草案的內容、涵蓋的產品範圍，及其對業界與目前市售產品的影響，茲整理會議中討論之內容，以 Q & A 方式簡述如下：

. 法案概述

- 該法案的目的為何？

  該法案的制定，是為了在歐盟境內建立一個協和化的「傳統植物藥產品」管理架構，應用於產品上市的核准，及提供業界一個單一化的產品註冊過程。其目標除了要保障民眾的健康外，同時也要移除造成歐盟地區醫藥品發展障礙的法規差異。

  當傳統植物藥產品無法達到歐盟現有醫藥品法規下，有關藥品上市許可的要求時，倘申請者可提供有關該產品於傳統使用、安全及品質的證據，則可申請傳統使用註冊（traditional use registration）。

- 各會員國及歐盟對於本法案推動所擔負之任務為何？

a. 本法案通過後的 18 個月內，各會員國必須落實實施（約於 2005 年九月）

b. 歐盟 EMEA 將於 2004 年成立一個新的植物藥產品委員會（Committee for Herbal Medicinal Products），該委員會將提供新的科學專家顧問群來評估藥用植物，建立植物藥產品核准之指引原則，並制定「positive list of herbal substances」。未來只要是在該 positive list 內的 herbal substances，在申請傳統使用註冊時，都不需再提供有關傳統使用及安全性的證明。

2. 該法案涵蓋之產品範圍

- 該法案涵蓋之產品範圍有哪些？

該法案適用之產品範圍為「活性成分來自植物」之產品（故非植物來源之傳統藥品--如動物類或礦物類的中藥材，將不適用本法案），但倘一個植物藥產品可以達到目前有關藥品上市的要求條件（即有效性、安全性及品質都可被證明），則不在本法案涵蓋之範圍內，而應依一般藥品上市途徑處理。

【備註】：所謂「活性成分來自植物」之產品並不包括由植物單離出化學成分所製造之產品。

- 一些比較強效的植物藥是否也可申請「傳統使用註冊」？

申請傳統使用註冊的植物藥將只限於那些不須醫療執業人員介入，病患就可自行使用的安全產品。

- 哪些劑型的植物藥產品可以申請傳統使用註冊？

申請傳統使用註冊的植物藥產品僅限於口服、外用及吸入劑型。

- 該法案是否允許植物藥結合營養補充物（如維生素、礦物質）的產品？

是的，該法案允許植物藥結合維生素、礦物質等營養補充劑的產品，只要申請者能證明其產品的安全性，以及添加的營養物其作用是與主成分之植物藥相輔相成的。這條路徑將帶給業界尋求已久的「彈性」，並且也對一些原本主要用途就是用於營養補充的傳統草藥有助益。

3. 傳統使用（traditional use）的定義

- 一個產品必需必須有多少年以上的使用經驗才符合「傳統使用」的定義？

申請者必須能夠證明其申請傳統使用註冊之植物藥（或其他與之相當的、可供比較的產品）在歐盟地區已經有三十年以上的藥用歷史；倘在歐盟地區的使用經驗多於十五年但不及三十年，可以舉證在歐盟以外地區的使用經驗。然而，有一點需要注意的就是，來自其他地區的傳統使用證明可能不足以提供適當的安全性證據（例如該地區缺乏藥物不良反應監視系統，或是該地區的人種與歐盟地區的人種差異過大）。

- 當使用其他相當的、可供比較的產品（comparable/corresponding products）來驗證一個申請中的產品確屬傳統使用時，該 comparable product 的成分是否須與欲申請的產品完全相同？

Comparable product 的成分不必與欲申請的產品完全相同，但是二者必須有相同的活性成分（active ingredients）、相等的藥效、相同或類似的用途及給藥途徑。

- 當證明一個產品是傳統使用時需要什麼樣的證據？

申請者必須提供可證明其產品為傳統使用的文獻或是經驗證據。有關證據的可能來源非常廣泛，包括中草藥的權威文獻、來自歐盟會員國市場上的許多有許可證（licensed）或無許可證（unlicensed）的產品之實際證據、許多會員國的衛生主管機關所認可的具有長久使用經驗的植物藥，以及來自中草藥學專家之作證。最後一種證據來源在確認植物藥合併使用的模式時，可能特別有幫助。而對於在 CHMP 之 positive list 內的 herbal substances，申請者則不需再提供有關傳統使用及安全性的證明。

4. CHMP 之 positive list 簡介

Committee on Herbal Medicinal Products（簡稱 CHMP，為歐盟 EMEA 下設立之科學性委員會）制定 positive list 之目的是為了幫助申請者免於再去提供一些已為大眾熟知且接受之傳統草藥其有關傳統使用及安全性的證據，減少不必要的麻煩。在這個議定的 list 中將涵蓋一些具有傳統使用歷史的 herbal substances 其治療的適應症、藥效強度、給藥途徑及其他相關的安全資訊，使申請者可以參照。但須注意的是，倘申請的植物藥產品其成分是在 positive list 內，申請者雖可不必再提供有關傳統使用及安全性的證據，但仍需提供其產品品質的證明。

5. 關於有效性（efficacy）之要求

- 傳統藥品是否需證明其效能才能申請傳統使用註冊？

在這個法案中已經清楚地說明，申請者不需提供證明產品有效性之臨床試驗數據。然而本法案要求申請者必須提供該植物藥在歐盟地區至少使用三十年以上的證據，這似乎暗示該植

物藥也有一些藥效上的證據。為反應這種情況，產品的包裝上將加註這樣的標示:「本產品的藥效未經臨床證實，而是根據長期使用的經驗」。

- 倘植物藥產品的功效可被證實，其定位又是如何?

當一個藥品的有效性、安全性及品質都可被證明，且經衛生主管機關判定可以達到目前有關藥品上市的要求條件時，則該藥品就不應申請傳統使用註冊，而應依一般藥品申請上市的途徑處理。

6. 關於安全性（safety）之要求

- 該法案對於產品安全性之主要要求有哪些？

申請者必須提供有關該產品的安全性資料，如文獻回顧、專家報告等。衛生主管機關並可依安全性評估之需要，要求申請者提供更多之數據。有關該類產品安全性最重要的考量就是：該類產品包括其適應症都必須達到即使沒有醫療人員監督，病患仍可自行使用的安全要求。

7. 關於品質（quality）之要求

- 該法案對於產品品質之主要要求有哪些？

有關該類產品的品質要求原則和一般領有許可證的藥品是相同的，它們都必須遵從藥品優良製造規範（Good Manufacturing Practice；GMP），並擁有藥品製造或販售的許可證。有關歐盟植物藥品優良製造規範（the European guidelines on Good Manufacturing Practice for herbal medicines）及歐盟藥典對於植物藥產品的品質規範都已普遍地被歐盟地區的業者

所採用，所以並無該法案中之品質規範難以適用於植物藥產品之理由。而所有的品質規範都是為了要確保產品的成分正確、無污染，以及品質安定可靠。(很難有充分的理由去界定一般藥品和傳統使用的藥品間不同的品質標準，因為在一些情況下，這二類產品的區分是一個灰色地帶。例如：一個擁有數種適應症的植物藥，可能其中一種適應症的療效是被確立，而可申請一般藥品註冊，而同時其他未經臨床確立療效的適應症則較適合傳統使用註冊。)

- 標準化的植物抽出物產品是否被該法案所允許？

是的，但該產品必須和原植物藥有相等的藥效強度，且必須證明該產品並未超出傳統使用劑量。

8. 產品的標示與廣告管理（labeling and advertising）

- 經註冊為傳統使用的植物藥產品，其包裝標示應包含哪些內容？

該類產品的標籤及仿單必須和一般藥品一樣，可提供消費者有關安全使用的資訊及指引，並且明確地告訴消費者「產品的藥效尚未經臨床證實，而是根據長期使用的經驗」，及提醒消費者在使用該類產品後，若症狀依然沒有改善，就應該諮詢醫師或醫療專業人員。

- 關於該類產品廣告之規範要求有哪些？

有關該類產品廣告之規範和一般領有許可證的藥品是相似的，並且該類產品的所有廣告都必須加註下列標語：「本傳統植物藥產品適用於（何類）適應症，其療效尚未經臨床證實」。

9. CHMP 簡介

CHMP 的全名是「Committee on Herbal Medicinal Products」，為歐盟 EMEA 於 2004 年新設立之科學性委員會，其主要功能為建立整個歐盟地區植物藥產品核准之指引原則，提供專家顧問群來協助 EMEA 有關植物藥產品核准上市前之科學性評估。未來該委員會並將制定「positive list of herbal substances」，在這個 list 中將提供一些具有傳統使用歷史的植物藥其治療的適應症、藥效強度、給藥途徑及其他相關的安全資訊，使 traditional use registration 的申請者可以參照，而免去提供一些早為大眾熟知且接受之傳統草藥其傳統使用及安全性的證據。

CHMP 是由每個會員國各推派一名代表所組成，每位代表的任期是三年。在 CHMP 成立的同時，EMEA 內原有的 Herbal Medicinal Products Working Party 仍然持續在運作，雖然這二者日後必須整合在一起，不過整合的工作還得花上一段時間。而目前 Herbal Medicinal Products Working Party 已經開始一些事前的準備工作，如 herbal monographs 的建立，這將是未來整個歐盟用於核准植物藥產品的重要依據。

簡而言之，在歐盟新的草藥管理架構實施後，中草藥在歐洲之發展趨勢將以 OTC、self-Medication 等保健相關產品為主，處方用藥為輔。而中草藥具有傳統使用歷史，在品質與安全性無慮者，其查驗登記將依產品的性質而有不同的要求標準。

（2）藥品優良臨床試驗規範之查核（**GCP inspection**）在歐美執行的現況

「藥品優良臨床試驗規範」(Good Clinical Practice, GCP）乃為確保藥品臨床研究的品質，所訂定的規範，其精神主要是保障受試者的權益，及確認試驗結果的品質，所以要求試驗執行時的每一個

步驟都必須留下紀錄，以供事後驗證。也就是說，凡發生過的必留下紀錄；未留下紀錄則代表未曾發生。根據 GCP 的定義，查核（inspection）是指主管機關正式檢閱其認為與臨床試驗相關的檔案、設備、紀錄、與其他可能在試驗機構、試驗委託者或受託研究機構之資源，或其他主管機關認為適當的設備，以決定臨床試驗相關活動的進行、數據紀錄、分析與報告是否均依照試驗計畫書、試驗委託者的標準作業程序、藥品優良試驗準則與相關法規的要求。

歐盟自 1996 年七月開始採用 ICH-GCP，而其與 GCP 議題有關的法規有下列二者：

1. Directive 2001/20/EC – clinical trials
2. Directive 2001/83/EC – Code for human medicinal products; Mark. Authorization

其中，Directive 2001/20/EC on clinical trials 之內容主要為 GCP 及試驗用藥品 GMP 之法規標準、定義受試者的權益及其保護原則，與明訂一個臨床試驗從開始到執行之主要步驟的程序。而 Directive 2001/83/EC – Code for human medicinal products 的內容主要則是申請醫藥品上市許可、製造、輸入、以及醫藥品不良反應通報的規範。

由於臨床試驗是成本很高的投資，倘若執行的品質不佳，即使未被主管機關察覺，將來勉強上市後再由市場上收回，則藥廠的損失更為慘重。因此如何確保臨床試驗的品質，是歐盟和歐洲藥業的共同目標。對於查核的作業方式，歐盟的 EMEA 是由確保品質的角度來進行，而不是由尋找缺失的角度來看，其重點放在如何預防缺失的發生。歐盟在進行有關受試者保護方面的查核時，其重點為：「受試者的保護措施可否被擔保？」而在臨床研究品質的查核方面，其重點則為：

1. 所收納的受試者其條件是否符合計畫書所訂定的標準？
2. 治療組間是否可互相對照？
3. 受試者的治療與處置是否被適當地管理？
4. 試驗數據（有效性、安全性數據）收集的品質如何？
5. 試驗結果如何被處理分析？
6. 藥品不良反應是否被有系統地呈報？

在歐盟地區，一個試驗用藥品（investigational medicinal products）是否依循 GCP 及 GMP 規範，可由各會員國來進行查核，而查核的結果在各會員國之間是互相承認的，並且也可提供查核報告給試驗贊助廠商（屬機密文件），以及有實際需求原因之衛生主管單位及人體試驗倫理委員會。但就如同藥物核准的途徑一樣，在歐盟地區查核也可分為 Non-centralized Procedure（互相認證途徑）與 Centralized Procedure（中央認證途徑）。Non-centralized Procedure 是根據歐盟各國主管單位間互相承認的原則來進行，也就是說一個會員國的 GCP 及 GMP 查核報告，是被其他會員國所承認的，倘若第一個會員國的認證不被其他會員國所承認，則有爭議的項目將會送交至 EMEA 進行裁決。而 Centralized Procedure 則是透過 EMEA 的查核部門來進行，其查核又可分為藥品上市前與上市後之查核：

1. 藥品核准上市前的查核（Pre-authorization inspection）

   EMEA 下設立的 Committee for Proprietary Medicinal Product（CPMP）受理查核案件後，在 90-120 天內完成初步審核，並於展開現場實地查核的前五天內通知申請者（查核進行當中案件處理天數將停止計算），而查核結束後，individual site reports 將會在 15 天內送給被查核者，針對查核報告中所提出之問題，被查核者可以提出申覆說明。最後，查核總結報告將在案件受理後的 150 天內彙整遞交 CPMP，由 CPMP 提供科學性的建議，作為 EMEA 是否核准該藥品上市之參考。

2. 藥品核准上市後的查核（Post-authorization inspection）

主要是藥品不良反應通報（pharmacovigilance）的查核。

實施 GCP 查核的優點是可以持續提昇臨床試驗的品質，預防未來缺失的發生。但反之，對於查核不合格的案件，也會造成其產品上市的申請被駁回或是暫時中止，或是導致試驗贊助者、研究者或委託合約研究機構受到民事或刑事的訴訟。不過從另一個觀點來看，查核確實可有效地提昇試驗贊助者、研究者或委託合約研究機構對受試者保護的責任感。

美國藥物食品管理局（U. S. Food and Drug Administration, FDA）的 GCP 查核歷史則更悠久，最早可追溯至 1962 年開始的 early clinical investigator inspections，1977 年再推動 Bioresearch Monitoring Program，1978 年實施醫院人體試驗醫學倫理委員會（IRB）的查核，而 1980 年起更開始實施 international clinical investigator inspections，對跨國性臨床試驗進行品質認證。

由於執行跨國性臨床試驗的查核迄今已有超過二十年的歷史，FDA 在這方面可說是經驗相當豐富，而跨國性試驗的查核結果將作為該研究結果可否採信之參考。自 1980 年至 2003 年間，FDA 共執行了 523 件跨國性臨床試驗的查核，依查核件數統計，最多的是加拿大的 107 件，其次分別為英國 78 件、法國 39 件、德國 37 件、義大利 27 件、瑞典 26 件、荷蘭 19 件、南非 18 件、比利時 16 件、西班牙 14 件、芬蘭 13 件。而俄羅斯、波蘭、匈牙利、捷克等東歐新興國家近年來受西方先進國家所委託執行的臨床試驗案件數也急速增加，成為 FDA 未來海外查核的重點（東歐地區首件接受 FDA 查核的試驗案件是 1994 年在波蘭所執行的，之後在東歐所執行的案件數迅速增加，1994-1997 年 FDA 在東歐執行了 5 件臨床試驗案件的查核；1998-2002 年增加為 18 件；到了 2003 年

時，光是該年度就受理了 14 件試驗案件的查核，顯示東歐地區臨床試驗的發展有迎頭趕上西歐國家的趨勢)。另外值得一提的是，在 523 件查核的跨國臨床試驗案件中，台灣亦執行了一件

FDA 執行海外查核之目的在於決定支持該藥品未來在美國上市的試驗數據可否被接受，因此試驗主持人及試驗委託者被查核的主要內容就是 data auditing。也就是說查核重點放在 data 本身及 data analyses 上，而不是放在 expert reports 及 summary statements 上。不論是國內或是海外的 GCP 查核，對 FDA 而言都是沿用同一套 SOP（Compliance Programs），所有的查核都涵蓋了下列意圖：

1. 對受試者的保護（human subject protection），包括易受傷害的族群（vulnerable populations）
2. 了解該計畫是否在符合法規的情況下執行（compliance with regulations）
3. 對訴怨作回應（responding to complaints）
4. 了解該項新發明（understanding innovations）
5. 給予輔導並評量其表現（education and performance measures）

根據 FDA 之統計，其 2002 至 2003 年共執行了 65 件國際性 GCP 查核（international inspection），查核合格率為 68 % ，而歐洲地區的查核合格率則為 62 % 。針對歐洲地區 GCP 查核不合格案件所作的分析顯示，不適當的紀錄及試驗設計為最常見的缺失原因（約佔 50 % ），其次為藥品不良反應通報之疏失（約佔 24 % ）、藥品管理不當（約佔 18 % ），以及受試者知情同意書方面的缺失（約佔 12 % ）。

有關於美國境外執行的臨床試驗結果可否被 FDA 接受，端視其是否依循所有美國的 IND 相關規範來執行，包括：

1. 21 CFR Part 312: IND Regulations

2. 21 CFR Part 50: Informed Consent Regulations
3. 21 CFR Part 56: IRB Regulations

在2001年3月FDA更公告了「Guidance for Industry, Acceptance of Foreign Clinical Studies」，在這份指引中，FDA便說明Non-U.S., non-IND trial可能獲得FDA受理產品上市審查，只要這些試驗符合下列原則：

1. 試驗結果適用於美國人種
2. 該試驗經過嚴謹的設計及執行
3. 該試驗是由合格的試驗主持人所執行
4. 該試驗是在遵守全球的倫理規範原則下進行
   - Minimal standard: Principles of the 1989 version of the Declaration of Helsinki (Drug/Biologics); Principles of the 1983 version of DOH (Medical Devices)
   - Local standards (e.g., ICH GCP in ICH regions) if these provide greater protection to subjects
5. 可接受FDA的查核

目前FDA正考慮是否要再進一步修訂2001年所公告的「Guidance for Industry, Acceptance of Foreign Clinical Studies」，以將一些新的或是修正的標準及要求納入。

總而言之，FDA GCP Program的策略是基於一種危機管理的精神，認為當一個研究計畫有較大之潛藏危機時，就需要被更多的關注，例如當易受傷害的族群被列為試驗對象、研究經費贊助者同時身兼試驗主持人，或是發現試驗主持人為了贊助廠商的利益而有欺瞞行為時。因為倘若一個藥品經由不法的途徑取得上市許可，則將來可能發生的社會風險更高。未來FDA希望能夠與美國境內及他國的查核主管機關共同分享經驗、交換資訊並增加對談，共同為國

際上查核員的培訓貢獻一己之力。

## 參、 心得

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、羅主任秘書淑慧及林高級研究員育娟給予機會，使本出國計畫得以成行。此外，亦十分感謝林主任委員耐心指導報告人，於出發前做好充分準備---不論是對大會議題的相關研究或是與會中重要來賓、官員、專家學者之交流應對，方能使本次出國計畫獲得較好之成果，報告人從參與本次國際會議中亦學習到不少寶貴的經驗。

本次行程收穫頗豐，除了與美國 FDA、歐盟官員及大會講員等有良好之交流外，並與這些重量級人士交換名片，及將中醫藥委員會與台灣中草藥臨床試驗環境簡介致贈給對方。其中，於大會中主持「歐盟對植物藥產品未來的立法架構」專題之 AESGP 的 general director -- Dr. Cranz 對本會的角色頗感興趣，當報告人正與其他講員交談、介紹我國中醫藥委員會並遞上名片時，Dr. Cranz 在一旁聽到了，也主動遞上名片交換，令報告人十分驚訝。由於長期參與歐盟對中草藥產品的立法及管理，Dr. Cranz 對傳統中醫藥認識頗多，亦曾多次赴北京考察參訪，與大陸藥政管理單位互動十分密切，惟其尚未到過台灣參訪。Dr. Cranz 並表示，日後 DIA 大會中有關中醫藥方面的主題，或許可以邀請本會人員演講。

中國大陸官方對於參與此類國際會議似乎也十分積極，甚至組團參加(其參與人員主要來自 State Food and Drug Administration / Center for Drug Evaluation, SFDA / Pharmacopoeia Commission of P.R. China 等相關單位)，惟本次會議從開幕直至閉幕，甚至在社交場合中，均未見到前述人士出席，令人十分不解。姑且不論這是否為大陸代表公費出國開會的普遍常態，大陸國家藥政管理單位和歐盟及 DIA 的關係還是十分密切的。報告人本次接觸到的一些美國 FDA 及歐盟官

員，均表示曾為中草藥的研發或法規管理、臨床試驗環境與品質等議題，實地到大陸考察訪問過。未來在大陸所進行的臨床試驗，其結果將渴望被這些先進國家所承認接受。而 DIA 2004 年第一季的 Drug Information Journal 中更刊載了一篇專文「The Regulation and Approval of New Drugs in China」，內容講述大陸藥政管理單位和藥政法規自 1985 至 2002 年以來的變革。在此文中亦分析，以一個臨床試驗基地而言，中國大陸提供了一個有競爭力、低花費且 patient base 龐大的利基。近年來，一些大型的國際合約研究機構（contract research organizations；CROs）也紛紛進駐中國大陸，並同時引進了一些國際大規模多中心臨床試驗，尤其在中國加入 WTO 後，這個市場顯得更加活躍。這些試驗在實施過程中嚴格按照國際 GCP 及標準化程序進行操作，其具有質量控制和質量保證的研究結果已達到國際認可的規範要求，為中國大陸 GCP 的建立實施和臨床研究水平的提昇，產生了十分積極的作用。

上述現象在匈牙利、捷克等東歐新興國家及俄羅斯也同樣存在，並成功地瓜分了西方先進國家臨床試驗產業的大餅。報告人在參觀 DIA 大會的展覽攤位時，拿到了一份俄羅斯當地合約研究機構的宣傳資料，上頭寫著：「我們是俄羅斯首家獨立臨床研究單位（clinical research unit），設於聖彼得堡醫學院附設醫院，擁有最人性化的舒適環境及最先進之醫療設備，於 2003 年依據 EC standard 重新改建落成，我們遵循 GCP 規範，並與衛生部門的法規單位互動良好。在這裡除了可使用醫院的各種設備及實驗室的服務外，對於一些複雜的醫學檢驗，我們也與聖彼得堡毒理研究所合作，其檢驗報告是被全球所公認接受的。本 CRU 可提供 24 小時 on site 醫療監測，受試者並接受嚴格之飲食控制，我們具備所有您預期一個 leading phase 1 unit 應有的設備，包括試驗藥局及電腦化的 study scheduling system，可確保您的試驗計畫有效率地依限完成。我們有超過 5000 名志願受試者的

廣大資料庫，這些受試者族群包括停經後婦女、老年人、高血壓患者、氣喘患者、糖尿病患者、不同人種的族群，以及吸煙及非吸煙族群。為了協助您收納特殊的病患族群，我們也與 State Healthcare Network 合作。本中心提供的服務項目包括各期臨床試驗、藥動學、生體相等性及生體可用率研究，及藥物、食品交互作用的研究等。當您選擇本 CRU 進行臨床試驗時，您將感受到高品質且高效率的服務、完全的信任，以及良好的溝通，更重要的是您的每一分錢都將花得非常值得.....」以上種種，使報告人深刻體驗到，台灣要「建立國內臨床試驗產業，成為國際級的新藥臨床試驗基地」其最大的競爭對手在哪裡。

在本次大會中，亦巧遇我國財團法人醫藥品查驗中心（CDE）朱執行長。朱執行長表示，對於此類大型國際會議，CDE 向來十分重視，歷年也都派人參加，使台灣終於在國際上逐漸獲得發聲的機會。最成功的例子為，第三十八屆 DIA 年度大會中，CDE 陳恆德副執行長獲邀演講「亞太地區臨床試驗環境與法規」，並且聯合我國相關藥政管理單位及衛生署補助設立之新/中藥臨床試驗中心，於會場中設置展示攤位，獲得廣泛迴響。而 1998 年陳副執行長獲 DIA 之邀，以客座主編的身分為 Drug Information Journal 編輯一本增補專輯，題目為「臨床試驗在亞太地區的最新進展」；2003 年其再度對過去五年來亞洲地區在此方面的急速發展，做了一番回顧與見證，並進一步擴展該本新專輯的主題為「亞洲在全球新藥發展和國際醫藥法規協和會趨勢中之角色」。由於 CDE 的鋪路及廣結善緣，本會也從中獲益，在本次大會中，CDE 朱執行長即陪同報告人拜會多位 DIA 大老。

參加本次年會後，深感我國受限於政治、外交因素，有許多國際組織無法參與，然科技新知、國際法規卻是每日不斷地推陳出新，故更應積極參與國際性研討會，有助於提昇能見度，並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。此外，也應積極培訓具有相關科技背景、熟悉政府相關政策且外文流利之人才，俾利國際交

流暨日後獲邀至國際性會議演講。

另有感於歐盟的擴展與整合使得該區域的發展變得更加快速，且有效提昇其全球競爭力，而亞洲雖有眾多人口，但這個區域內的國家其藥品市場大多很小，藥政單位均不強且較缺乏臨床試驗的基礎建設，故未來勢必要以國際法規協合會（International Conference Harmonization；ICH）的精神來協調各國，將亞洲整合成單一市場，提供協和的法規環境以利新藥研發，提昇該區域的製藥工業發展，並保障民眾的健康。

## 肆、建議

### 一、對國內中草藥產業發展之建議

在歐盟新的草藥管理架構實施後，中草藥在歐洲之發展趨勢將以OTC、self-Medication 等保健相關產品為主，處方用藥為輔。而中草藥具有傳統使用歷史，在品質與安全性無慮者，其產品查驗登記將依產品的性質而有不同的要求標準。故建議國內業者可先從食品方面的研發著手，主動找到充分證據，再慢慢提升至藥的層次，而未來以植物結合維生素或礦物質的營養補充品，也是一種新的產品出路。由於中草藥在德、法、英等歐洲國家已有多年使用經驗，在歐洲民眾自我健康照護意識抬頭，草藥、OTC 及保健藥品市場逐年增長下，歐洲不啻為我們下一個市場開拓之地。建議未來國內在舉辦中草藥發展相關產學座談會時，可考慮邀請如歐盟 AESGP、EMEA 的 Herbal Medicinal Products Working Party 或 Committee for Herbal Medicinal Products 之專家學者來分析歐洲市場，並更進一步介紹歐盟的中草藥管理及查驗登記辦法，讓國內業者一起來思考如何切入這片廣大的市場。

此外，傳統中藥倘要進軍國際市場，其品質必須先達到均一再現。然中藥的藥材原料許多來自天然物植物，其有效成分易受天然環

境及人工栽培影響而導致變異性大，因此對其品質的掌控確實有困難度存在；再加上台灣百分之九十之中藥材從大陸地區進口，難以掌握生產地的實際狀況，加上這些藥材運至台灣時多已經過修治、初步加工或炮製，更增加其鑑定及品質掌握上之因難。因此如何協助業界掌握藥材資源及品質，為未來台灣中藥產業能否永續發展的第一步。本會於九十三年度開始推動的「建構中藥用藥安全五年計畫」，其內容包括中藥境外暨境內管制中心的建立、亞太中藥標準品供應中心的建立、中草藥製程、製劑、機儀器開發計畫等，相信將會對國內中藥品質的提昇有很大的助益。此外，近幾年來，分子生物技術、化學分析方法，及生物活性測試技術皆突飛猛進，政府應鼓勵將這些技術開發應用於中藥品質的管控，以確保產品的一致性。總而言之，建立一套中藥材、中藥製劑的品質規格標準及相關技術平台，為未來拓展國際市場的必備條件之一。

二、對發展國內臨床試驗產業之建議

藥品研發是一項高成本、高風險、耗時且受到極度規範的產業，整個研發的過程涉及許多專業的整合，從基礎研究、動物試驗、臨床試驗到生產上市。而其中最關鍵的步驟就是臨床試驗的導入，此階段之目標在證實藥品使用於人體之安全性及有效性。而臨床試驗的報告資料，為各國衛生主管機關評估與核可藥物上市的關鍵。

根據統計，一個成功上市的藥品平均需投資達五億美金，耗費十五年的時間，而其中臨床試驗的過程就佔了整個藥品開發時程的三分之二，其資金之溢注約達上市前總研發經費的 60-70% 。故國際研發性藥廠在選擇臨床研究的合作對象時，考慮的條件依次為高品質、高效率以及低成本。

目前國際藥品研發的主要來源為美國、歐洲與日本，在歐美以外地區的投資以美國及歐洲藥廠為主，合計該二者每年在歐美以外地區

的臨床試驗投資金額達 1100 億新台幣，是台灣可以立即競爭的市場機會。為建立我國完整之中藥臨床試驗體系與機制，促進新藥研發，並協助國內中藥臨床試驗產業的建立，使台灣成為國際級的中藥新藥臨床試驗基地，本會依據行政院核定之「加強生物產業推動方案」與「中草藥產業技術發展五年計畫」，自九十年度起積極展開相關工作，陸續完成「中藥臨床試驗中心」、「中醫藥聯合人體試驗醫學倫理委員會」與「中草藥不良反應通報系統」的建置、臨床試驗人才的培訓，並研修中藥新藥查驗登記準則與審查流程規範，以及重要疾病之中藥臨床試驗基準。自九十一年度起，更開始推動中藥臨床試驗 GCP 查核，嚴格管理臨床試驗之品質。目前各中藥臨床試驗中心不論在執行臨床研究之能力、人員的訓練以及配合的環境，都已具備相當的基礎。但是為了與其他國家競爭國際臨床試驗的大餅，我們還必須檢視自己的長處與短處。

近年來，由於優良臨床試驗規範的國際共同標準已經相當成熟，不同地區所產生的研究資料可以被互相採用，因此所有的跨國研發性藥廠都積極地尋找能夠有效率又低成本完成試驗的合作對象，並積極投入開發有潛力的地區。所以中國大陸及東歐的一些新興國家，挾其低花費與 patient base 的利基，正逐漸地瓜分全球臨床試驗產業的大餅。反之，台灣因國民所得較高的關係，不論是在臨床試驗的花費或是自願受試者的族群數目方面，都無法與前述國家競爭，所以台灣競爭的利基到底在哪裡？

報告人覺得台灣的優勢在於擁有素質優良整齊的臨床醫療人員、便利的醫療環境，以及和歐美先進國家比較之下相對不高的研究花費，再加上執行臨床研究的能力已經具備一些基礎，故未來台灣的臨床試驗產業應該走向精緻化，繼續提昇執行效率、增進管理能力並合理控制成本，從此點切入成功機會將大大提昇。而未來我國的中藥新藥法規環境也應與國際接軌，並提昇審查效率及統一審查規範（審

查員的訓練亦應與國際同步），使新藥研發在台灣更容易進行，吸引國際藥廠引進大型研究計畫，並帶動本地藥品發展的週邊產業，創造優良的研發環境。而透過參與大型跨國性臨床研究，台灣也可汲取各時期臨床臨床試驗之經驗，加強規劃及執行各期藥物臨床試驗的能力，以協助國內新開發藥物進入臨床試驗發展階段並掌握藥品核准商品化之關鍵性步驟，奠定台灣成為國際級的新藥臨床試驗基地之基礎。

三、我國應加強與國際之交流互動

一如其他的產業，中草藥產業必須要有夠大的市場做為依據，才能存活，進而發展，因此台灣要發展中草藥產業，「國際化」是一個無可替代的選擇，尤其隨著全球經濟一體化進程的加快，及西方藥廠的大規模投入，中草藥市場融入國際醫藥大市場的廣度和深度劇增，因此我們必需正視主流市場的規範體系及市場標準。我國因受限於政治、外交因素，有許多國際組織無法參與，而科技新知、國際法規是每日不斷地在推陳出新，故建議應更積極參與國際研討會，與各國專家學者作良好之互動，俾建立日後交流互訪之基礎。此外，政府也應積極培訓具有相關科技背景、熟悉政府相關政策且外文流利之人才，俾利國際交流暨日後獲邀至國際性場合演講，宣揚政府的政策理念，及開拓中藥產品在國際市場的商機。

四、建立友善之英文化環境俾利國際交流

為使政府的政策行銷可以達到國際化的水準，並因應國際交流所需，建議相關政策宣傳品應加強英文化與國際化，而本會的英文版網頁內容亦需比照中文網頁再充實加強，以提供有興趣了解的國際人士一個友善的查詢環境。此外，報告人在參加本次國際會議時發現，許多醫藥衛生組織、政府機構及業界代表均隨身攜帶其機構之簡介或宣傳品，以便與國際人士交流時致贈給對方。這不但是一種禮儀，也可

能是未來雙方建立互動的基礎。本次報告人出國前即自行準備了一些有關台灣中草藥臨床試驗環境與法規之英文版簡介，事後證明十分受用。惟建議日後本會相關出版品以及重要政策的行銷資料應加速英文化，並隨時保持足夠之庫存量（尤其是本會業務之英文版簡介），以供外賓來訪時致贈及提供給參加國際會議的同仁使用。上述宣傳資料倘需由出國同仁自行準備印製，將較為克難，並且與國際場合上其他單位發放的文宣比較起來，印製也較不精美。

在這二十一世紀，具有傳統文化特色和獨特優勢的中草藥正面臨前所未有的發展機遇與挑戰，此時政府應扮演積極的角色，建立相關的平台技術、規範體系，及現代化的審核標準等，以「國際化」為總體目標，具體落實與先進國家規範標準接軌之目的，才能使我國的中草藥產業獲得永續發展的契機。

## 伍、附錄

附錄一　第十六屆 DIA 歐洲年會議程

附錄二　第十六屆 DIA 歐洲年會壁報論文摘要

附錄三　The future Committee on Herbal Medicinal Products

附錄四　Improving the legal framework for herbal medicinal products in European Union

附錄五　GCP inspections in Europe

附錄六　FDA GCP update

# 附錄一

DIA®

DRUG INFORMATION ASSOCIATION

# 7TH ANNUAL EUROMEETING

## PRAGUE 2004

EXPANDING HORIZONS - HOPES AND CHALLENGES

MARCH 10-12, 2004

CONGRESS CENTRE, PRAGUE, CZECH REPUBLIC

## Programme Advisors

**Rolf Bass**
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**Andrzej Czarnecki**
Eli Lilly & Company Ltd., UK

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State Institute for Drug Control, Czech Republic

**Panos Tsintis**
EMEA, UK

**Noël Wathion**
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## Programme Co-chairpersons

**Yves Juillet**
Les Entreprises du Médicament (LEEM)
France

**Birka Lehmann**
Belgium

## Programme Committee

**Iman Barilero**
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**Gaby Danan**
Aventis Pharma, France

**Françoise de Crémiers**
Wyeth Research, France

**Günter Hennings**
hgh regulatory sciences, Germany

**Brenton James**
GlaxoSmithKline R&D, UK

**Gill Le Du**
ICON Consulting, UK

**Andrea Rappagliosi**
Serono International S.A., Switzerland

**Jennifer Sims**
Novartis Pharma AG, Switzerland

**Rolf Spang**
Swiss Agency for Therapeutic Products, Swissmedic, Switzerland

**Dagmar Stará**
State Institute for Drug Control, Slovak Republic

**Josep Torrent Farnell**
Fundació Dr. Robert, Spain

**Lincoln Tsang**
Arnold & Porter, UK

**Anu Tummavuori-Liemann**
F. Hoffmann-La Roche Ltd., Switzerland

**Joachim Vollmar**
PRA International, USA

**Susanne Wedderkopp**
Novo Nordisk A/S, Denmark

## From the Programme Co-chairpersons

Dear Colleagues and Friends,

It is our pleasure and honour to welcome you to the16th DIA EuroMeeting

***Expanding Horizons - Hopes and Challenges***

on behalf of the Programme Committee.

In 2004, the EU will expand to include new Member States. As a symbol of this historic occasion, the 2004 DIA EuroMeeting will take place in Prague, for centuries a European capital of cultural, industrial, and commercial activities. Given the date and the location of the meeting in Prague, a specific meeting track will be devoted to EU enlargement.

The aim of the Prague 2004 EuroMeeting is to provide an opportunity for participants to better understand how internationalisation is changing the ways in which research, development, registration, and the launch of new medical products are handled.

This meeting has been organised to allow each participant to improve his or her professional expertise and to directly interact with distinguished representatives from regulatory authorities, academia, and industry.

Meeting tracks will cover drug discovery and new technologies, quality and manufacturing, emerging nonclinical themes, regulatory issues in the EU and at the international level, clinical trials and therapeutic areas, statistics and data management, pharmacovigilance, and epidemiology. Other tracks will address project management and outsourcing, which have become more critical, as have public health, patient access to medicines and orphan drugs, and special populations.

Generics, OTC, and medical devices will also be covered in the programme, as will EU enlargement. All aspects of this important challenge will be covered in eight different sessions.

Internationalisation and harmonisation will impact directly on each of our activities. Let us try together to be prepared to face these new opportunities and challenges.

We hope that this programme will meet your needs. It has been built for you, and with the kind participation of many of you who have proposed interesting themes.

**Yves Juillet** **Birka Lehmann**

## Wednesday, March 10, 2004

# Plenary Session / Ask the Regulators
# Award Ceremony / Reception

**14:00 - 15:15** **Plenary Session Part I**

**DIA Welcome and Introduction of the Mayor of Prague, Dr. Pavel Bém**
Eleanor Perfetto, DIA President and The Weinberg Group Inc., USA
Wayne Nitchuk, Director, DIA European Branch Office, Switzerland

**Welcome by the Mayor of Prague**

**Introduction by the Programme Co-chairs**
Birka Lehmann, Belgium
Yves Juillet, Les Entreprises du Médicament, France

**Plenary Speaker**
Paul Weissenberg, European Commission, Belgium

**Keynote Speaker**
Ernesto Bertarelli, CEO of Serono International S.A., Switzerland and America's Cup Winner 2003

**15:15 - 15:45** **Coffee Break**

**15:45 - 17:15** **Plenary Session Part II - Ask the Regulators***

Philippe Brunet, European Commission, Belgium
Thomas Lönngren, EMEA, UK
Daniel Brasseur, Chairman of CPMP, Belgium
Milan Smid, State Institute for Drug Control, Czech Republic
Josep Torrent-Farnell, Chairman of COMP, Spain

**17:15 - 18:00** **DIA Distinguished Career and Outstanding Services Award Ceremony**

**Black and White Theatre Performance with Music**

**18:00 - 21:00** **Buffet Reception in the Prague Congress Centre**

** The "Ask the Regulators" session will be interactive, without introductory remarks from the speakers and only a short explanation from the moderators, Birka Lehmann and Yves Juillet. The audience will be encouraged to participate, and questions for specific speakers can be forwarded prior to the actual session.*

# Table of Contents

## ALL TUTORIALS WILL TAKE PLACE ON WEDNESDAY, MARCH 10, 2004, FROM 09:00 TO 12:30

# TUTORIALS

### Tutorial 1

**SUCCESSES, CHALLENGES AND PITFALLS IN THE NONCLINICAL DEVELOPMENT OF BIOTECHNOLOGY PRODUCTS TO SUPPORT EARLY CLINICAL TRIALS**

Tutorial Chairperson:
**Jennifer Sims, Novartis Pharma AG, Switzerland**

*Tutorial Description*
This tutorial will bring together industry and regulatory experts in the field of nonclinical development of biotechnology products and review the information required to support early clinical development. Using a case study approach to illustrate the successes, challenges and pitfalls in nonclinical development, the critical drug substance and drug product quality aspects and preclinical safety programme to support early clinical development will be discussed. The impact of the EU Clinical Trials Directive on early clinical trials with biotechnology products will also be considered. Is it possible to go from "gene-to-POC" in 12 months?

**Introduction**
Jennifer Sims, Novartis Pharma AG, Switzerland

**CMC Challenges in Early Preclinical and Clinical Development**
Chris Holloway, ERA Consulting, UK

**Regulatory View on Preclinical Support for Early Clinical Trials and the Impact of the Clinical Trials Directive on Trials in Europe**
Jan Willem van der Laan, Medicines Evaluation Board, The Netherlands

**Challenges in Preclinical Development Illustrated by Case Studies**
Roly Foulkes, Celltech R&D, UK

**Case Studies: Hurdles and Pitfalls in Vaccine**
François Verdier, Aventis Pasteur, France

**Challenges in Preclinical Development Illustrated by Case Studies**
Janet Clarke, Biogen, USA

**What Does the Clinician Want to Know?**
David Glover, Cambridge Antibody Technology, UK

### Tutorial 2

**THE COMMON TECHNICAL DOCUMENT (CTD) AND eCTD: LESSONS LEARNED AND SHARED EXPERIENCES**

Tutorial Chairperson:
**Françoise de Crémiers, Wyeth Research, France**

*Tutorial Description*
The tutorial on the CTD and eCTD experience will address practical issues regarding the different CTD modules, i.e. Quality/Biotech, Preclinical and Clinical.
Speakers from industry and authorities will share their experience and will answer questions from the audience.
The eCTD experiences will also be presented and issues will be discussed.

**EMEA Premeeting Submissions - Experiences**
Hilde Boone, EMEA, UK

**The CTD Quality Part**
Jean-Louis Robert, Laboratoire National de la Santé, Luxembourg

**The CTD Nonclinical Part**
Gerd Bode, Altana Pharma, Germany & Klaus Olejniczak, BfArM, Germany

**The CTD Clinical Part - Case Studies**
- Europe
  Celine Melcion, Aventis Pharma, France
- USA
  Michael Brennan, GlaxoSmithKline, USA

**eCTD - An Enormous Challenge to Adopt and a Potential Approach**
Krishan Arora, USA

**Panel Discussion**
Moderator: Barbara van Zwieten-Boot, Medicines Evaluation Board, The Netherlands

### Tutorial 3

**OVERVIEW OF VACCINES-DEVELOPMENT AND MARKETING**

Tutorial Co-chairpersons:
**Daniel Brasseur, Ministry of Public Health, Belgium**
**Anne-Marie Georges, GlaxoSmithKline Biologicals, Belgium**

**Use of New Adjuvants in Vaccines: Rationale and European Data Requirements**
Roland Dobbelaer, Scientific Institute of Public Health-Louis Pasteur, Belgium

**Clinical Development of a Rotavirus Vaccine**
Johan Van Hoof, GlaxoSmithKline Biologicals, Belgium

**Efficacy Endpoints for the Conjugate Vaccines: Strepto Pneumoniae, HiB, Meningo with a Special Attention to Different Antibodies and Cut-off Levels Used to Predict Protection, and a Discussion on the Potential Need for a Booster Dose**
Bernard Fritzell, Wyeth-Lederle, France

**Building an Efficient Vaccinovigilance System in the European Union**
Daniel Brasseur, Ministry of Public Health, Belgium

**Vaccines Manufactured in the European Union that are Intended for Third World Countries Only - How to Get them Authorised?**
Anne-Marie Georges, GlaxoSmithKline Biologicals, Belgium

## ALL TUTORIALS WILL TAKE PLACE ON WEDNESDAY, MARCH 10, 2004, FROM 09:00 TO 12:30

# TUTORIALS

### Tutorial 4

**KEY ELEMENTS OF THE EU REGISTRATION PROCEDURES FOR ACCESSION MEMBERS**

Tutorial Co-chairpersons:
**Dagmar Stará, State Institute for Drug Control, Slovak Republic**
**Anu Tummavuori-Liemann, F. Hoffmann-La Roche Ltd., Switzerland**

*Tutorial Description*
This tutorial will provide a pragmatic overview of how the EU registration procedures work, presented by representatives from regulatory authorities and industry.

**CP Registration Process**
Elina Hannuksela, AstraZeneca Oy, Finland
Anthony Humphreys, EMEA, UK

**MRP Registration Process**
Truus Janse-de Hoog, Medicines Evaluation Board, The Netherlands
Sara McLean, Roche Products Ltd., UK

### Tutorial 5

**EXPERIENCE WITH IMPLEMENTATION OF MedDRA AND PHARMACOVIGILANCE**

Tutorial Chairperson:
**Elliot Brown, Elliot Brown (Consulting) Ltd., UK**

*Tutorial Description*
This advanced interactive tutorial covers many of the key areas concerning the effective use of the Medical Dictionary for Regulatory Activities in the monitoring and reporting of drug safety. It includes the use of MedDRA in searching safety databases, signal detection, expedited reporting and PSURs and touches on such issues as clinical trial safety data analysis, labelling and version management.

### Tutorial 6

**PRINCIPLES OF STUDIES FOR THE STATISTICAL VALIDATION OF DIAGNOSTIC TESTS**

*Has been cancelled*

### Tutorial 7

**IMPLEMENTATION OF A PHARMACOGENETICS/PHARMACOGENOMICS PROTOCOL IN CLINICAL TRIALS**

Tutorial Chairperson:
**Nadine Cohen, Johnson & Johnson Pharmaceutical R&D, USA and member of Pharmacogenomics Working Group**

*Tutorial Description*
The term "genomics" encompasses a global scientific asset, using molecular biology and genetic tools for the determination of the genome (DNA) or its products (RNAs, proteins). Pharmacogenomics applies this information to drug design, discovery, and clinical development. The impact of genetic differences on therapeutic use is what the science of pharmacogenetics aims to unravel. The analysis of a broad set of genetic markers may show that a genotypically defined subgroup of subjects with a certain disease may have a higher probability of responding to a certain drug differently from others in the population. The rationale for the pharmacogenetic approach is that the observed genotype and/or gene expression may correlate with, and explain, some of the differences in efficacy and side effects including adverse reactions to medicines in humans. However, it is important to have realistic expectations with reference to pharmacogenetic clinical research. At present, with very few exceptions, pharmacogenetics is unlikely to be a primary determinant of clinical decisions. This tutorial will teach you step by step how to conduct a pharmacogenetics study as part of a drug development clinical trial.

**Pharmacogenomics: Basic Concepts and Selection of the Approach**
Nadine Cohen, Johnson & Johnson Pharmaceutical R&D, USA

**The Pharmacogenetic Protocol and Informed Consent Form**
Julie Friedman, Bristol-Myers Squibb, USA

**Pharmacogenomic Study Design Considerations**
Sandra Kirkwood, Eli Lilly, USA

**Interpretation of the Data and Clinical Implications**
Brian Spear, Abbott, USA

**Industry and Regulators Use and Perception of Integrating Pharmacogenetics (PGt) and Pharmacogenomics (PGx) in Drug Development**
Carly Anderson, CMR International, UK

**Panel Discussion with the Participation of Eric Abadie, AFSSAPS, France, and Larry Lesko, FDA, USA, and speakers Rick Hockett, Eli Lilly, USA and John Ryan, Wyeth, USA**

**Message from Regulatory Authorities to Industry**
Larry Lesko, FDA, USA

**Message from Regulatory Authorities to Industry**
Eric Abadie, AFSSAPS, France

**Questions and Answers**
- From regulators to industry speakers
- From industry speakers to regulators
- From participants to all panelists

## ALL TUTORIALS WILL TAKE PLACE ON WEDNESDAY, MARCH 10, 2004, FROM 09:00 TO 12:30



### Tutorial 8
**HOW TO MAKE A SUCCESSFUL APPLICATION FOR AN Rx-TO-OTC SWITCH IN EUROPE**

Tutorial Chairperson:
**Bernd Eberwein, German Medicines Manufacturers Association (BAH), Germany**

*Tutorial Description*
Self-medication is nowadays generally accepted as an important part of healthcare. It is in line with the growing desire of people to take more responsibility for their own health. When practised correctly self-medication can also save expenses for the national health care systems.
For industry, self-medication is also an opportunity for the prolongation of the life cycle of a product. A precondition for self-medication is an Rx-to-OTC Switch. An application file including comprehensive data must be submitted to the decision-making body for this procedure. Competent speakers will present the European Switch Guideline and will provide useful information (e.g. case reports) on how to manage a successful switch application.
Aspects of a possible interference between Rx and reimbursement conditions will also be covered.

**How to Use the European Switch Guideline and How to Solve Problems in Application Procedures**
Bernd Eberwein, BAH, Germany

**What Can We Learn from Case Studies? (Switch Cases, SPC Harmonisation, Are There Different Switch Cultures in the EU?)**
Cheryl Hall, Johnson & Johnson MSD, UK
Horst Kastrup, Viatris, Germany

**Council of Europe Policies in the Legal Classification of Medicines - Forerunner and Pioneer?**
Sabine Walser, Council of Europe, France

**The Political Impact of the EU System of Classification of Medicines**
Hubertus Cranz, AESGP, Belgium

### Tutorial 9
**NONCLINICAL SAFETY SCREENING IN THE DRUG DISCOVERY PHASE**

Tutorial Chairperson:
**Per Spindler, BioImage A/S, Denmark**

*Tutorial Description*
With a high number of drug candidates failing in preclinical development and clinical trials due to metabolism, pharmacokinetic problems and/or toxicity, there is an urgent need to develop and implement experimental systems for accurate prediction of human drug toxicity. Many techniques are already implemented in drug R&D, e.g. computer models, in vitro assays such as cell- or tissue-based assays, and the techniques are used early in the drug discovery process in a cost-effective and strategic manner.

Per Spindler, BioImage A/S, Denmark
- Overview of the drug discovery process and the experimental systems for early safety assessment: integrating early safety assessment with late stage safety assessment
- Assessment of the impact for discovery/development projects
- Predictive value of methods: Computer models - in vitro ADMET - cell-based assays - tissue-based assays - in vivo (animal ADME and toxicology) - human/patients

Pauline Gee, MDS Pharma Services, USA
- Predictive Chemogenomics Strategies

Stephan Chevalier, Pfizer, France
- Combining Panomics Data to Investigate Toxicological Effect: Example of Drug-induced Vasculitis

Lutz Müller, Novartis Pharma AG, Switzerland
- Validation/assessment of methods
- Structure-based predictions of genotoxicity and toxicity
- Integrating in vitro genotoxicity screens into the drug discovery process
- Finding a predictive toxicogenomic screen
- From predictive screens to identification of biomarkers
- Case study

**Questions and Answers / Panel Discussion**

## ALL TUTORIALS WILL TAKE PLACE ON WEDNESDAY, MARCH 10, 2004 FROM 09:00 TO 12:30

# TUTORIALS

### Tutorial 10
**PHARMACEUTICAL PROJECT MANAGEMENT - A QUICK HEALTH CHECK**

Tutorial Co-chairpersons:
**John Faulkes, TeamCommunications Development, UK**
**Ralph White, PPMLD Ltd., UK**

*Tutorial Description*
Pharmaceutical Project Management Learning and Development

Delegates will be asked a series of diagnostic questions designed to determine the health of a pharmaceutical development project. Technical aspects of the project (target profile, risk identification and contingency planning) and human factors (project leadership, teamwork) will be explored in an interactive session that actively encourages reflection on the state of a project.

This tutorial is intended for those relatively new to product development - not only project managers, but also functional managers interested in knowing more about the development process. It will generate practical ideas that can be applied at regular intervals in the workplace such as at milestone reviews.

### Tutorial 11
**POPULATION PK/PD STUDIES: INTRODUCTION, BIOSTATISTICAL RECOMMENDATIONS AND GUIDANCE**

Tutorial Co-chairpersons:
**Harry Mager, Bayer AG, Germany**
**Joachim Vollmar, PRA International, USA**

*Tutorial Description*
Population PK/PD modelling merges computational and statistical approaches with pharmacokinetics and pharmacodynamics. The tutorial is positioned for those relatively new to pharmacometric modelling - not only statisticians and project managers, but also functional managers interested in acquiring some knowledge on what population PK/PD may contribute to drug development.

**PK/PD Models**
Ruedi Port, German Cancer Research Centre, Germany

**Pharmacometric Approaches to Population PK/PD Modelling Underlying Assumptions and Principles**
Harry Mager, Bayer AG, Germany

**Useful Diagnostics in Population PK/PD Modelling**
Niclas Jonsson, University of Uppsala, Sweden

### Tutorial 12
**APPLIED PHARMACOEPIDEMIOLOGY FOR INVESTIGATIONS OF SAFETY SIGNALS**

Tutorial Chairperson:
**Monika Pietrek, PRA International, Germany**

*Tutorial Description*
Pharmacoepidemiology, the study of the use and the effects of drugs on a large number of people, has become an integral part of drug safety management. This tutorial explains how pharmacoepidemiology contributes to the identification and evaluation of safety signals, how risks can be quantified and which data sources are available.

**Investigating Safety Signals**
Monika Pietrek, PRA International, Germany

**Measuring Risks**
Stephen J.W. Evans, London School of Hygiene & Tropical Medicine, UK

**Data Sources for Investigations**
Monika Pietrek, PRA International, Germany

### Tutorial 13
**SETTING UP A DRUG SAFETY DEPARTMENT**

Tutorial Chairperson:
**Andrzej Czarnecki, Eli Lilly & Company Ltd., UK**

*Tutorial Description*
The tutorial is targeted at emerging biotech companies, CROs and academic institutions. The talks will focus on the requirements for safety monitoring during drug development and post approval with regard to processes, resources, skills, tools and organization. The safety tasks considered will include safety management plans for SAE and ADR handling as well as annual update and PSUR generations. The tutorial will distinguish essential from nice-to-have features. Options for in- and outsourcing will be discussed.

With Irina Baeumer, PRA International, Germany

### Tutorial 14
**CDISC: PROGRESS ON DATA STANDARDS FOR CLINICAL TRIALS FROM BEGINNING TO END**

Tutorial Chairperson:
**Rebecca Kush, CDISC, USA**

The Clinical Data Interchange Standards Consortium (CDISC), a not-for-profit organization founded in 1997, has developed standards to support the acquisition, exchange, submission and archive of electronic data to facilitate clinical trials. These standards are open, platform-independent and vendor-neutral. Information on the progress of CDISC and international adoption and usage of the CDISC standards will be presented. Specific tutorial focus will be on:

- The CDISC Submission Data Standards Version 3.1 and implications with respect to the FDA Guidance on eSubmissions and the eCTD;
- The collaboration of CDISC and Health Level Seven (HL7) and standards to support XML-based data transfer from standard protocol elements through regulatory submissions.

**Speakers:**
*Charles Jaffe, AstraZeneca, USA*
*Rebecca Kush, CDISC, USA*
*Pierre-Yves Lastic, Sanofi-Synthelabo, France*
*Udo Siegmann, Parexel GmbH, Germany*

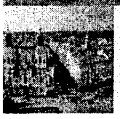
## Track 1

**Drug Discovery and New Technologies**
Iman Barilero, Johnson & Johnson Pharmaceutical R&D, UK
Lincoln Tsang, Arnold & Porter, UK

## Track 2

**Clinical Trials and Therapeutic Areas**
Françoise de Crémiers, Wyeth Research, France
Jacques Mascaro, Johnson & Johnson Pharmaceutical R&D, UK

## Track 3



**Project Management and Outsourcing**
Gill Le Du, ICON Consulting, UK
Susanne Wedderkopp, Novo Nordisk A/S, Denmark

## Track 4

**EU Regulatory Environment**
Brenton James, GlaxoSmithKline R&D, UK
Christa Wirthumer-Hoche, Federal Ministry of Health and Women, Austria

## Track 5

**EU Enlargement**
Dagmar Stará, State Institute for Drug Control, Slovak Republic
Anu Tummavuori-Liemann, F. Hoffmann-La Roche Ltd., Switzerland

## Track 6

**International Regulatory Issues**
Rolf Bass, BfArM, Germany
Stéphane Callewaert, EFPIA, Belgium

## Track 7

**Statistics and Data Management**
Joachim Vollmar, PRA International, USA

## Track 8

**Clinical Safety and Pharmacovigilance**
Gaby Danan, Aventis Pharma, France

## Track 9

**Emerging Nonclinical Issues**
Jennifer Sims, Novartis Pharma AG, Switzerland

## Track 10

**Quality Issues and Manufacturing**
Stuart Heir, Novartis Pharma AG, Switzerland
Rolf Spang, Swissmedic, Switzerland

## Track 11

**Medical Devices**
Martine Delétraz-Delporte, Faculty of Pharmacy of Grenoble, France
Roger Grase, BfArM, Germany

## Track 12

**Public Policy and Patient Access to Medicines in Europe**
Andrea Rappagliosi, Serono International S.A., Switzerland

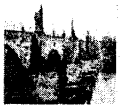
## Track 13

**Public Health, Patient Needs and Orphan Drugs**
Andrea Rappagliosi, Serono International S.A., Switzerland

## Track 14

**OTC/SM and Herbal Products**
**Generic Medicinal Products**
Günter Hennings, hgh regulatory science, Germany

## Track 15



**Special Populations**
Ingrid Klingmann, Pharmaplex, Belgium
Klaus Rose, Novartis Pharma AG, Switzerland

***Statements made by speakers are their own opinion and not necessarily that of the organisation they represent or that of the Drug Information Association.***

***Speakers and agendas are subject to change without notice.***

***Audiovisual taping of any DIA workshop or session is prohibited without prior written consent from DIA.***

## Drug Discovery and New Technologies

Iman Barilero, Johnson & Johnson Pharmaceutical R&D, UK
Lincoln Tsang, Arnold & Porter, UK

THURSDAY, MARCH 11, 2004

**08:00 Welcome Coffee and Registration**

**09:00 Session 1**

**GENETICS AND PERSONALISED MEDICINE, MANAGING DRUG DEVELOPMENT IN THE POST-GENOMIC ERA**

**Session Chairperson:**
**Tom Chu, Roche, USA**

*This session will review the underlying scientific opportunities for the integration of genomic diagnostics into drug discovery, development and life-cycle strategies and will characterise the underlying opportunities for value creation associated with such. In light of the inherent predictive elements of "personalised medicines," consideration will also be given to the additional requirements for drug development planning to ensure the co-delivery of relevant and informative genomic diagnostics.*

**Pharmacogenomics Application in Drug Discovery and Development Target Identification**
*Joachim Reischl, Schering AG, Germany*

**Personalised Medicine: Implications for the Drug Development Process**
*Jorgen Dirach, Novo Nordisk A/S, Denmark*

**Prediction and Prescription - Exploring the Economic Implications of Pharmacogenetics**
*Lisa Bradley, Roche, USA*

**Update from CIOMS Working Group on the Issue of Drug Development and Cost**
*Juhana E. Idänpään-Heikkilä, CIOMS, Switzerland*

**10:30 Coffee Break in the Exhibition Area**

**11:00 Session 2**

**PHARMACOGENOMIC-GUIDED DRUG DEVELOPMENT: REGULATORY AND RESEARCH POLICY PERSPECTIVES**

**Session Chairperson:**
**Eric Abadie, AFSSAPS, France**

*The application of pharmacogenomics and pharmacogenetics in drug development is developing rapidly to advance innovative changes in prediction of the risks of diseases and in deciding the best use of drug treatments. The genomic and genetic technologies also impact on drug development strategies and costs and regulatory assessment of new therapeutic products. The session will address the regulatory perspectives and current initiatives regarding the integration of pharmacogenomics in the drug development process and will discuss genetic research policy and societal considerations.*

**Regulatory Perspective**
- EU Views
  *Marisa Papaluca, EMEA, UK*
- Submission of PG Data for FDA Review
  *Larry Lesko, FDA, USA*

**Industry Perspective**
*Ronald Salerno, Wyeth, USA*

**Genetic Research Policy and Societal Considerations**
*Celia Brazell, GlaxoSmithKline, UK*

**12:30 Lunch in the Exhibition Area**

**14:00 Session 3**

**ENSURING DIAGNOSTIC STANDARDS FOR GENETICALLY-INFORMED DRUG DEVELOPMENT**

**Session Chairperson:**
**David Jefferys, MHRA, UK**

*This session will describe and discuss the regulation and diagnostic standard for tests which will underpin genetic and personalised medicine, and also consider the development of pharmacogenomics-based diagnostic tests.*

**Regulatory Perspective on Regulating Diagnostic Tests**
*Steve Gutman, FDA, USA*

**A View from the Diagnostics Industry**
*Andy Bufton, Abbott Diagnostics, UK*

**Development of Pharmacogenomics-based Diagnostic Tests: Practicality, Applications and Challenges**
*David Atkins, Ortho-Clinical Diagnostics, USA*

**15:30 Coffee Break in the Exhibition Area**

**16:00 Session 4**

**COMPARABILITY OF BIOTECHNOLOGICAL/BIOLOGICAL PRODUCTS**

**Session Chairperson:**
**Pierrette Zorzi-Morre, AFSSAPS, France**

*Manufacturers of biological medicinal products can make changes to their products and processes during development and during the postmarketing phase in order to improve or optimise a manufacturing process, to improve product stability, or to make changes in order to comply with new regulatory requirements. General guidance for demonstrating comparability between prechange and postchange products has been provided in the CPMP Note for Guidance on comparability that came into force in March 2001. Comparability is also under consideration within ICH. However, further guidance is still needed to assess the impact of a change in quality attributes for a given product on its safety and its efficacy. The session will provide an update on the current regulatory and scientific situation in addressing the issue of comparability (e.g. preclinical and clinical annex to CPMP NfG of comparability, new ICH Q5E document, FDA guidance/considerations). The session will provide an expert perspective on the issue, including the current thinking at the EMEA and FDA level.*

**EMEA NfG on Comparability and Annex Update**
*Pekka Kurki, National Agency for Medicines, Finland*

**ICH Q5E Update**
*Alan Morrison, Celltech, UK*

**Resolving Scientific and Regulatory Considerations in the Assessment of Comparability**
*Anthony Mire-Sluis, FDA/CDER, USA*

**Panel Discussion with Jean-Hugues Trouvin, AFSSAPS, France**

**17:30-18:30 Reception in the Exhibition Area**

**Drug Discovery and New Technologies**
Iman Barilero, Johnson & Johnson Pharmaceutical R&D, UK
Lincoln Tsang, Arnold & Porter, UK

FRIDAY, MARCH 12, 2004

**09:00 Session 5**

**(Joint Session with Track 9 Session 5)**
**IMMUNOGENICITY OF BIOTECHNOLOGY-DERIVED THERAPEUTIC PRODUCTS**
**Session Chairperson:**
**Iman Barilero, Johnson & Johnson Pharmaceutical R&D, UK**
*The majority of biotechnology-derived therapeutic products exhibit some level of immunogenicity, with clinical sequelae that vary from having no adverse clinical consequences to severe adverse events, depending on the product and its indication. The investigation of immunogenicity is evaluated by measuring levels of specific anti-product antibodies. However, results are wholly dependent on the design and the analysis of the assay. The aim of this session is to explore the safety problems associated with immunogenicity, to address some considerations in designing studies to investigate immunogenicity, and to provide some insight into current regulatory decision making on immunogenicity testing, a risk-based approach. A target risk-assessment, product/specific pharmacovigilance management plan will be discussed. Representatives from industry, FDA, EMEA and Member States will provide their views and experiences on this important issue.*

**Preclinical and Clinical Considerations**
*Cindy Wong, Medical Products Agency, Sweden*

**Current Regulatory Decision Making on Immunogenicity Testing: A Risk-based Approach?**
*Anthony Mire-Sluis, FDA/CDER, USA*

**Postmarketing Surveillance and Risk Management Plan**
*John Knight, Johnson & Johnson Pharmaceutical R&D, USA*

**Panel Discussion with Pekka Kurki, National Agency for Medicines, Finland**

**10:30 Coffee Break in the Exhibition Area**

**11:00 Session 6**

**BIOSIMILAR MEDICINAL PRODUCTS**
**Session Co-chairpersons:**
**Anne-Marie Georges, GlaxoSmithKline Biologicals, Belgium**
**John Purves, EMEA, UK**
*There is currently an attempt to create a regulatory framework for similar biological medicinal products, in particular through the revision of Directive 2001/83/EC and its recently approved annex, Directive 2003/63/EC. The changes in the regulation will have an impact on the thinking and activities in the biological sector, including their implications on future Member States within the scope of enlargement. In addition, the CPMP is working on an on-going basis on relevant scientific guidelines dealing with this issue. The framework could be further clarified in terms of criteria for demonstrating similarity between a second-generation biological medicinal product claimed to be similar to one already on the market. The session will address the challenges of using the information available from the regulatory framework to demonstrate similarity. Will this framework be clear enough?*

**New Provisions in the EU Law and Implications for the Accession Countries**
*Roland Dobbelaer, Scientific Institute of Public Health-Louis Pasteur, Belgium*

**How to Define the Appropriate Safety and Efficacy Data**
*Jacques Mascaro, Johnson & Johnson Pharmaceutical R&D, UK*

**The Development Pathway for Comparable Biotechnology Products**
*John Greenwood, GeneMedix plc, UK*

**12:30 Lunch in the Exhibition Area**

**14:00 Session 7**

**GENE THERAPY**
**Session Chairperson:**
**Jean-Hugues Trouvin, AFSSAPS, France**
*Although there has been scarce evidence to show the potential for gene therapy to treat certain life-threatening diseases, it should be recognised that we are still at the stage of developing gene transfer products and evaluating their safety and efficacy. Adverse events have implicated certain types of gene transfer products (essentially viral vectors) and have prompted a number of actions regarding risk management and refinement of the delivery systems for the sake of patient safety. This session will focus on the current clinical development with gene therapy products, risk evaluation and management, and related regulatory issues.*

**Gene Therapy Perspectives: Promises, Failures and Pitfalls**
*Philippe Leboulch, Massachusetts Institute of Technology, USA*

**Safety Monitoring and Risk Management**
*Lincoln Tsang, Arnold & Porter, UK*

**Current Regulatory Development and Achievements - CPMP Gene Therapy Working Group**
*Marisa Papaluca, EMEA, UK*

**15:30 Coffee Break in the Exhibition Area**

**16:00 Session 8**

**CELL THERAPY**
**Session Chairperson:**
**Lincoln Tsang, Arnold & Porter, UK**
*There have been technological advances that have paved the way for the therapeutic use of cell- or tissue-based products. The development of such products will present new technical, regulatory, legal and bioethical challenges. There is currently a lack of certainty and clarity about how such products should be classified and regulated within the existing legal framework. There are also new bioethical issues regarding the sourcing of tissues and cells as well as their administration to the patients. There will also be a rethink of the strategy for patient safety monitoring for cell- or tissue-based products. This session will attempt to address some of these questions.*

**Regulatory and Legal Aspects**
*Lincoln Tsang, Arnold & Porter, UK*

**Bioethical Consideration**
*Colin Gavaghan, University of Glasgow, UK*

**Safety Monitoring and Regulatory Guidance**
- EU Point of View
  *Pekka Kurki, National Agency for Medicines, Finland*
- US Point of View
  *Celia Witten, FDA, USA*

**17:30 Close of the 16th Annual EuroMeeting Prague 2004**

## Clinical Trials and Therapeutic Areas

Françoise de Crémiers, Wyeth Research, France
Jacques Mascaro, Johnson & Johnson Pharmaceutical R&D, UK

## THURSDAY, MARCH 11, 2004

**08:00 Welcome Coffee and Registration**

**09:00 Session 1**

**CNS AND NEUROPATHIC PAIN GUIDELINES**
**Session Chairperson:**
**Barbara van Zwieten-Boot, Medicines Evaluation Board, The Netherlands**
*Up to now only a few medicinal products have been available for the treatment of neuropathic pain and most of them are used off label. Recent developments, however, indicate more interest in this area. At the CPMP level, a Note for Guidance is being developed focusing on patient populations to be included, endpoints and the indication. Concerning the latter, the possibility of extrapolating from one disease to another will be explored. This session will focus on these issues and ideas from regulators and industry will be discussed.*

**EU Health Authority Viewpoint**
*Cristina Sampaio, Instituto De Farmacologia e Terapeutica Geral, Portugal*

**Industry Viewpoint**
*Stefan Schwabe, Johnson & Johnson Pharmaceutical R&D, USA*

**Panel Discussion with Session Speakers and Jean-Pierre Lehner, Sanofi-Synthelabo, France**

**10:30 Coffee Break in the Exhibition Area**

**11:00 Session 2**

**SHOULD NEW DATA CHANGE THE OSTEOPOROSIS GUIDELINE? (HRT - DURATION OF CTS)**
**Session Chairperson:**
**Barbara van Zwieten-Boot, Medicines Evaluation Board, The Netherlands**
*Although the CPMP Note for Guidance on Osteoporosis in Post-Menopausal Women has been recently revised in 2001, new developments invite for a new update on this Guidance.*
*The place of estrogens is in discussion after new safety and efficacy data are published. The duration of the clinical trials should be re-discussed now that new data or new analysis show that for certain procedures the reduction on the risk of fractures can be found already after 12-18 months. The use of placebo in Phase 3 trials has been questioned by some experts. This will also be discussed.*

**Regulatory Impact on the Osteoporosis Guideline**
*Frits Lekkerkerker, Medicines Evaluation Board, The Netherlands*

**Presentation of the New Data**
*Francine Caulin, FC Consulting, France*

**Industry Viewpoint Regarding HRT Safety Issues and Reference Product**
*Mirjam Mol-Arts, NV Organon, The Netherlands*

**Panel Discussion with Session Speakers and with Markku Toivonen, National Agency for Medicines, Finland**

**12:30 Lunch in the Exhibition Area**

**14:00 Session 3**

**EUROPEAN DIRECTIVE ON CLINICAL TRIALS: CURRENT IMPLEMENTATION STATUS IN THE 15 MEMBER STATES AND IN THE INDUSTRY - PART I**
**ETHICAL ISSUES**
**Session Co-chairpersons:**
**Birka Lehmann, Belgium**
**Jacques Mascaro, Johnson & Johnson Pharmaceutical R&D, UK**
*The Clinical Trial Directive comes into force on May 1, 2004. The directive will bring new compliance challenges that require attention.*
*One of the stakeholders that has to modify its procedures in order to comply with the legislation is the Ethics Committee. The session will focus on the issues relating to the implementation of the directive from an Ethics Committee perspective, and will address important issues such as the European Ethics Committee network.*

**The Role of Ethics Committees**
*Francis Crawley, EFGCP, Belgium*

**The European Network of Ethics Committees**
*Barbara Rhode, European Commission, Belgium*

**The Industry Perspective**
*Kristel van de Vaorde, Bristol-Myers Squibb, Belgium*

**15:30 Coffee Break in the Exhibition Area**

**16:00 Session 4**

**EUROPEAN DIRECTIVE ON CLINICAL TRIALS: CURRENT IMPLEMENTATION STATUS IN THE 15 MEMBER STATES AND IN THE INDUSTRY - PART II**
**Session Co-chairpersons:**
**Françoise de Crémiers, Wyeth Research, France**
**Birka Lehmann, Belgium**
*This session will address EUDRACT practical implementation, GMPs and Clinical Trial application packages to ECs and CAs. The CTA will be discussed regarding possible CTD format and harmonized applications throughout Europe.*

**IMPs and GMPs: Site Certificate, CMC Documentation to ECs, IMPD, Importation, QP Responsibilities**
*Pierre-Henri Bertoye, AFSSAPS, France & Christine Gilissen, Ministry of Health, Belgium*

**Applications to Competent Authorities for CTAs - One or Many Application Packages?**
*David Bill, Wyeth Research, UK*

**Is the CTD Format Usable for Clinical Trial Applications?**
*Sandra Hecker, Hecker & Associates, USA*

**Panel Discussion with Session Speakers and Steve Hasler, GlaxoSmithKline Pharmaceuticals, UK**

**17:30-18:30 Reception in the Exhibition Area**

**Clinical Trials and Therapeutic Areas**
Françoise de Crémiers, Wyeth Research, France
Jacques Mascaro, Johnson & Johnson Pharmaceutical R&D, UK

FRIDAY, MARCH 12, 2004

**09:00 Session 5**
COMPLIANCE WITH GCP
**Session Co-chairpersons:**
**Claire Massiot, Sanofi-Synthelabo, France**
**Fergus Sweeney, EMEA, UK**
*Assessing compliance with GCP in the new European Clinical Trials Regulatory Environment:*
- *Impact of the EU Clinical Trials Directive on EU inspections - GCP inspection in Europe*
- *Parallel with USA-FDA approaches to GCP compliance assessment*
- *Approaches of pharmaceutical industry in GCP compliance assessment - risk management*

**GCP Inspections in Europe**
*Pierre Henri Bertoye, AFSSAPS, France*

**FDA GCP Update**
*David Lepay, FDA, USA*

**Risk Management Approach to GCP Compliance**
*Beat Widler, F. Hoffmann-La Roche Ltd., Switzerland*

**Panel Discussion with Session Speakers and Industry Speakers**

**10:30 Coffee Break in the Exhibition Area**

**11:00 Session 6**
DEVELOPMENT OF ONCOLOGY PRODUCTS (PART I)
**Session Co-chairpersons:**
**Jean-Michel Alexandre, Hôpital Européen Georges Pompidou, France**
**Stephane Andre, Wyeth Research, USA**
*The recent progress in understanding the various aspects of the molecular biology of tumor cells and overall, tumor pathology, have led to the discovery of numerous candidate drugs aimed at playing a role in the various existing chemotherapeutic treatments. Adequate development of these new-targeted agents needs to be conducted using novel surrogate endpoints for clinical efficacy based on pharmacological or pharmacodynamic features as well as population stratification or profiling. However, from a regulatory perspective the risk-benefit evaluation as single therapy or in combination therapy remained based on the clinical benefit which may be a variable criterion depending on the stage of the disease and the status of the patient. These two sessions will provide the viewpoints of regulators and industry on the development of these new drugs but will address also the regulatory considerations from the EU and the US for registering drugs in the refractory setting.*
- *Use of biological endpoints and surrogate markers in clinical trials for registering novel cancer treatment*
- *Clinical endpoints for registering treatment in refractory cancers (EU/US perspectives)*
- *Assessing combinations of cytotoxic and noncytotoxic cancer therapies*

**Biological Endpoints in Cancer Clinical Trials - Impact on Clinical Development and Regulatory Endpoints**
*Karol Sikora, Hammersmith Hospital, UK*

**Assessing Combination of "Cytotoxics" and "Noncytotoxics" - Consequences for Disease Treatment Strategies**
*Bertil Jonsson, Medical Products Agency, Sweden*

**Panel Discussion with Session Speakers and Industry Speakers (Jean-Pierre Bizzari, Sanofi-Synthelabo, USA)**

**12:30 Lunch in the Exhibition Area**

**14:00 Session 7**
DEVELOPMENT OF ONCOLOGY PRODUCTS (PART II)
**Session Co-chairpersons:**
**Jean-Michel Alexandre, Hôpital Européen Georges Pompidou, France**
**Stephane Andre, Wyeth Research, USA**

**Clinical and Regulatory Strategies for Refractory Cancer Treatments - An EU Perspective**
*Michel Marty, Institut Gustave Roussy, France*

**Clinical and Regulatory Strategies for Refractory Cancer Treatments A US Perspective**
*Steven Hirschfeld, FDA, USA*

**Panel Discussion with Session Speakers, Industry Speakers and Martine George, Johnson & Johnson Pharmaceutical R&D, USA**

**15:30 Coffee Break in the Exhibition Area**

**16:00 Session 8**
TELEMATICS
**Session Chairperson:**
**Steve Hasler, GlaxoSmithKline Pharmaceuticals, UK**
*A large programme of Telematics projects, in support of the European Regulatory Procedures, is being undertaken by the EMEA. This session will provide an overview of the projects ongoing or being planned and the strategy being followed. The session will concentrate on an update on the project to build and implement the Register of Clinical Trials, EudraCT, required by the EU Clinical Trials Directive.*

**Telematics Update from EMEA**
*Timothy Buxton, EMEA, UK*

**CT Directive Database - EUDRACT**
*Timothy Buxton, EMEA, UK & Steve Hasler, GlaxoSmithKline Pharmaceuticals, UK*

**Panel Discussion with Session Speakers**

**17:30 Close of the 16th Annual EuroMeeting Prague 2004**



## THURSDAY, MARCH 11, 2004

**08:00 Welcome Coffee and Registration**

**09:00 Sessions 1 and 2 combined**

COMPETENCY MAPPING AND DEVELOPING HIGH-PERFORMANCE TEAMS

**Session Co-chairpersons:**
**Gill Le Du, ICON Consulting, UK**
**Susanne Wedderkopp, Novo Nordisk A/S, Denmark**

*These sessions will provide inspiration from competency and developing mapping as applied to different organisations through practical examples. Furthermore, the sessions will include suggestions and discussions on applying the experiences in forming high-performance teams.*
*The last half of the sessions will be in roundtable style to give the attendees the opportunity to exchange their experiences and thoughts on how to map competencies and develop the best teams.*

**Competency Mapping in Project Management - Experiences and Visions**
*Allan Wehnert, Lundbeck A/S, Denmark*

**Competency Mapping in a Diverse Organisation - Practical Experience and Lessons Learned**
*Charlotte Lex, Novo Nordisk A/S, Denmark*

**Measurement of Competencies - Discussion of Different Methodologies and How Results are Interpreted**
*Gill Le Du, ICON Consulting, UK*

**Introduction to Roundtable Discussion**
*Susanne Wedderkopp, Novo Nordisk A/S, Denmark*

**10:30 Coffee Break in the Exhibition Area**

**11:00 Sessions 1 and 2 (continued)**
*The roundtable discussion will be followed by presentations in plenum where the attendees will be given the opportunity to present the highlights from their discussions.*

**12:30 Lunch in the Exhibition Area**

**14:00 Session 3**

THE PRESENT AND FUTURE SHAPE OF PROJECT MANAGEMENT IN PHARMA R&D

**Session Co-chairpersons:**
**Andrew Arzymanow, Pfizer Global R&D, UK**
**Terry Cooke-Davies, Human Systems Ltd., UK**

*What might a "breakthrough" model of project management look like for pharmaceutical R&D?*
*This session presents a provocative and innovative look at how development projects might be structured and managed, in order to deliver time and cost breakthroughs of the order accomplished in other industries, while recognizing the existence of real constraints typical to the pharma industry.*

**Developing the Breakthrough Model - Latest Results of Ongoing Research in Both Pharma and Other Industries**
*Terry Cooke-Davies, Human Systems Ltd., UK*

**The Shape of a "Breakthrough" Model for Project Management in Pharma, How It Might Look and How it Differs from Current Practice**
*Andrew Arzymanow, Pfizer Global R&D, UK*

**The Path to Breakthrough Performance. The Steps to be Taken and the Challenges to be Overcome by Organisations if They Implement the "Breakthrough" Model**
*Pauline Stewart-Long, GlaxoSmithKline, UK*

**15:30 Coffee Break in the Exhibition Area**

**16:00 Session 4**

KNOWLEDGE MANAGEMENT FOR CLINICAL TEAMS: IDENTIFYING TRAINING NEEDS

**Session Chairperson:**
**Sylvie Penine-Gouverneur, Wyeth Research, France**

*As a team member, have you ever been to a training session and wondered what you were doing there?*
*Even if the trainer is a good subject matter expert and has defined training objectives very clearly, you still feel frustrated and so may the other team members. In this session we will see how we can identify training needs for teams, how individual training can improve the team training quality, how a collection of well-trained individuals can become an effective team and how competencies and personal development can be measured.*

**Knowledge Management for Clinical Teams: Identifying Their Training Needs**
*Sylvie Gouverneur-Penine, Wyeth Research, France*

**Team Management of Knowledge and the Development of Open Communications are the Key to Identifying Training Needs and Satisfaction with the Training Process**
*Elliott Sogol, Campbell University, USA*

**How We Have Developed Online Measurement of Performance Competency and Personal Development: Case Study**
*Sue Harley, IQdos Limited, UK*

**17:30-18:30 Reception in the Exhibition Area**

## Project Management and Outsourcing

Gill Le Du, ICON Consulting, UK
Susanne Wedderkopp, Novo Nordisk A/S, Denmark

# FRIDAY, MARCH 12, 2004

**09:00 Session 5**

PROJECT PLANNER: A NEW ROLE ON THE PROJECT TEAM

**Session Chairperson:**
**Art Gertel, Beardsworth Consulting Group, USA**

*Effective clinical trial project management embodies two dimensions: clinical expertise and clinical trial management experience as well as experience in the practice of the science of formal project management. It is the rare project manager who possesses both skill sets. This panel will explore an alternative to the traditional "all-in-one" model in assessing the potential for a partnership of two individuals, each bringing expertise to fulfill the needs of the team. The panel will also discuss aspects of leading project teams in differing cultures.*

**Regional/Cultural Differences: Critical Factors in Planning and Conducting Successful International Clinical Trials**
*Milan Kovacevic, Alteon Inc., USA*

**Project Management and Planning: A Small Company Perspective**
*Ingrid Armstrong, Daiichi Pharmaceutical Corporation, USA*

**The Global Project Manager/Planner - Crossing Cultural Barriers: Global Trial Success through a Process of Integration**
*Nadina Jose, Research Strategies Inc., USA*

**10:30 Coffee Break in the Exhibition Area**

**11:00 Session 6**

PROJECT MANAGEMENT OUTSIDE PRODUCT DEVELOPMENT

**Session Chairperson:**
**Inger Mollerup, Novo Nordisk A/S, Denmark**

*Project management is obviously also useful outside the scope of development of new drugs. This will be illustrated through examples covering use of project management to control partnering/outsourcing projects, within regulatory agencies and for management of the life cycle phase of an approved drug.*

**Implementation of Project Management in the Regulatory Evaluation Process**
*Mike Morris, Irish Medicines Board, Ireland*

**Working with Uncertainty**
*Ralph White, PPMLD, UK*

**Improving Life Cycle Management**
*Inger Mollerup, Novo Nordisk A/S, Denmark*

**12:30 Lunch in the Exhibition Area**

**14:00 Session 7**

PROJECT MANAGEMENT IN THE "NEW EU" - CENTRAL AND EASTERN EUROPE

**Session Chairperson:**
**John Shillingford, IMFORM GmbH, Germany**

*Project management is defined and described in a number of different ways, all depending upon the needs and environment of the project. This session will explore three different project management processes driven by the differing requirements of circumstance with particular emphasis on projects focused on Central and Eastern Europe.*

**Central and Eastern Europe - Chances and Challenges for the Project Management of the Pharmaceutical Industry**
*Kurt Plichler, Sankyo Pharma GmbH, Germany*

**Project Management Experience in Central and Eastern Europe**
*Stefan Kupitz, IMFORM GmbH, Germany*

**Project Management in Russia and the Ukraine from a US Standpoint**
*Natalie Gershman, Geny Research Inc., USA*

**15:30 Coffee Break in the Exhibition Area**

**16:00 Session 8**

OUTSOURCING STRATEGIES OF SELECTING A CRO

**Session Chairperson:**
**Peter Davidson, ICON, UK**

*There will be three short presentations on the approach and philosophy of the process of selecting a CRO from the perspective of each of the following companies by the following discussants:*

*Carl Emerson, Celltech R&D Ltd., UK*
*Jane Lloyd, AstraZeneca, UK*
*Steve Martindill, Kyowa Hakko, UK*

*The different approaches will be compared in a wrap-up session.*

**17:30 Close of the 16th Annual EuroMeeting Prague 2004**

**EU Regulatory Environment**
Brenton James, GlaxoSmithKline R&D, UK
Christa Wirthumer-Hoche, Federal Ministry of Health and Women, Austria

THURSDAY, MARCH 11, 2004

**08:00 Welcome Coffee and Registration**

09:00 Session 1

**CENTRALISED PROCEDURE - THE ROLE OF THERAPEUTIC ADVISORY GROUPS (TAG)**
**Session Chairperson:**
**Sue Forda, Eli Lilly & Co., Ltd., UK**
*In this session, the function of therapeutic advisory groups in the evaluation of applications for marketing authorisations in the centralised procedure will be discussed from the perspective of rapporteurs, EMEA and industry.*

**Current Experience to Date of the Use of Therapeutic Advisory Groups**
*Marisa Papaluca-Amati, EMEA, UK*

**Industry Views on the Role and Function of Therapeutic Advisory Groups in the Current Centralised Registration Procedure**
*Christine-Lise Julou, EFPIA, Belgium*

**What Industry Expects of Therapeutic Advisory Groups in the Future Legislation for the Centralised Procedure after Implementation of the Regulation**
*Sue Forda, Eli Lilly & Co., Ltd., UK*

**10:30 Coffee Break in the Exhibition Area**

11:00 Session 2

**KEY ELEMENTS IN THE REGULATION OF THE NEW EUROPEAN MEDICINES LEGISLATION**
**Session Chairperson:**
**Paul Huckle, GlaxoSmithKline, UK**
*Major changes to the centralised procedure will be elaborated and discussed in detail.*

**Update from the Commission**
*Philippe Brunet, European Commission, Belgium*

**Impact on National Regulatory Agencies**
*Rolf Bass, BfArM, Germany*

**Impact on the Pharmaceutical Industry**
*Frances Charlesworth, AstraZeneca, UK*

**12:30 Lunch in the Exhibition Area**

14:00 Session 3

**CPMP SCIENTIFIC ADVICE AND PROTOCOL ASSISTANCE**
**Session Co-chairpersons:**
**Agnès Saint-Raymond, EMEA, UK**
**Markku Toivonen, National Agency for Medicines, Finland**
*The tasks and performance of the CPMP Scientific Advice Working Group (SAWG) will be reviewed based on experience gathered in its first year of functioning. The SAWG's experiences in giving Protocol Assistance are reviewed by a representative of the COMP and SAWG. Quality and impact of the advice will be discussed in the light of case studies.*

**Update on Activities of the Scientific Advice Working Group**
*Markku Toivonen, National Agency for Medicines, Finland*

**CPMP/COMP Protocol Assistance: Experience**
*Rembert Elbers, BfArM, Germany*

**CPMP Scientific Advice: Case Studies**
*Paul Huckle, GlaxoSmithKline R&D, UK*

**15:30 Coffee Break in the Exhibition Area**

16:00 Session 4

**KEY ELEMENTS IN THE DIRECTIVE 2001/83/EC - NONCENTRALLY APPROVED PRODUCTS**
**Session Chairperson:**
**Christa Wirthumer-Hoche, Federal Ministry of Health and Women, Austria**
*In this session the latest results on discussions about proposed changes in the Directive 2001/83/EC will be presented.*
*The pros and cons of important key elements of the Directive and their implications on the licensing procedures of medicinal products from the authority and industry point of view, taking into account the EU enlargement, will also be presented.*

**Latest News of the Review of Directive 2001/83/EC**
*Irene Sacristan-Sanchez, European Commission, Belgium*

**The Redesign of MRP - Will It Solve the Problem?**
*Christa Wirthumer-Hoche, Federal Ministry of Health and Women, Austria*

**Industry Point of View on the Review of the Directive**
*Barbara Sickmüller, BPI, Germany*

**MRP and DCP - Implications for the Applicant - A Critical Appraisal from an Industry Perspective**
*Kurt Ehlert, AstraZeneca, UK*

**17:30-18:30 Reception in the Exhibition Area**

**EU Regulatory Environment**

Brenton James, GlaxoSmithKline R&D, UK

Christa Wirthumer-Hoche, Federal Ministry of Health and Women, Austria

FRIDAY, MARCH 12, 2004

**09:00 Session 5**

**REFERRALS - WHICH WAY NOW?**

**Session Chairperson:**

**Tomas Salmonson, Medical Products Agency, Sweden**

*The outcome of the Anorectic's case creates uncertainties with regard to the legal status of an EC decision, following an Article 30/31 referral. Furthermore, there are a number of practical issues remaining, relating to the maintained harmonisation of products involved in the referral as well as the harmonisation of generics following an Article 30 referral for the innovator product. Nevertheless, the issues justifying these referrals will continue to exist. The aim of this session is to discuss how to move forward given the current and future legal situation.*

**From the Point of View of a CPMP Member**
*Tomas Salmonson, Medical Products Agency, Sweden*

**View of the EMEA: Past, Present and Future**
*Anthony Humphreys, EMEA, UK*

**Industry Point of View**
*Nicole Dillier, Novartis Pharma, Switzerland*

**10:30 Coffee Break in the Exhibition Area**

**11:00 Session 6**

**REGULATORY DATA PROTECTION**

**Session Chairperson:**

**Manuel Campolini, Addleshaw Goddard, Belgium**

*The new European legislation proposes changes on issues that are likely to impact product development decisions as well as on the market opportunities for generic products. In this context, one of the focal points of opposition between the innovative and the generic industries concerns the protection given to the registration dossier. The objective of this session will be to provide an update on this important topic as it stands at the time of the accession.*

**The Current and New Legislation: What Is Changing? Impact on the EU Enlargement**
*Irene Sacristan-Sanchez, European Commission, Belgium*

**The View of the Generic Industry**
*Nadene McClay, European Generic Medicines Association (EGA), Belgium*

**The View of the Innovative Industry**
*Anne Nielsen, Bristol-Myers Squibb, Belgium*

**12:30 Lunch in the Exhibition Area**

**14:00 Session 7**

**VARIATIONS**

**Session Chairperson:**

**Peter Bachmann, BfArM, Germany**

*Following the introduction of the new Variation Regulations (Commission Regulation (EC) No 1084/2003 and 1085/2003) for medicinal products authorised through Mutual Recognition and Centralised Procedure, first experiences have been gained. The pros and cons of the new Variation Regulations are discussed in this session from both sides - regulators and industry.*

**Practical Experience with Variations in the Centralised Procedure**
*Hilde Boone, EMEA, UK*

**Practical Experience with Variations in the Mutual Recognition Procedure**
*Shirley Norton, MHRA, UK*

**Practical Experience from the Industry Point of View**
*Monica Löfgren, Merck, Sharp & Dohme (Europe) Inc., Belgium*

**15:30 Coffee Break in the Exhibition Area**

**16:00 Session 8**

**TRANSPARENCY IN EUROPEAN PROCEDURES**

**Session Chairperson:**

**Daniel Brasseur, Ministry of Public Health, Belgium**

*An overview of the evolution of transparency at the EMEA during the last 2-3 years, with special attention on CPMP procedures and communication strategy will be presented. Expected further improvements are to be discussed.*

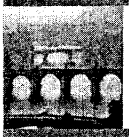
**Transparency Policy of the EMEA**
*Noël Wathion, EMEA, UK*

**CPMP/EMEA Communication with Patients**
*Frits Lekkerkerker, Medicines Evaluation Board, The Netherlands*

**Patient Point of View**
*Yann Le Cam, Eurordis, France*

**Industry Point of View**
*Ture Sjoblom, AstraZeneca, Sweden*

**17:30 Close of the 16th Annual EuroMeeting Prague 2004**



## EU Enlargement

Dagmar Stará, State Institute for Drug Control, Slovak Republic
Anu Tummavuori-Liemann, F. Hoffmann-La Roche Ltd., Switzerland

THURSDAY, MARCH 11, 2004

**08:00 Welcome Coffee and Registration**

**09:00 Session 1**

**REGULATORY IMPLICATIONS: FROM 15 TO 25 MEMBER STATES**

**Session Chairperson:**

**Milan Smid, State Institute for Drug Control, Czech Republic**

*Views on implications of enlargement of the European Union on regulatory practices in the enlarged EU will be presented and discussed by speakers from the European Commission, EMEA, national regulatory authorities and the pharmaceutical industry. The participants will be informed on measures adopted to facilitate the transition from 15 to 25 EU Member States and on perspectives of further development of EU regulatory framework, and how these are reflected in the amended EU pharmaceutical legislation. Key issues concerning the balance between interests of stakeholders in the enlarged EU, extent of centralised and national regulatory operations, use of telematic tools and databases inside EU regulatory network and access of EU citizens to medicinal products will be open for discussion.*

**Regulatory Framework in the EU Consisting of 25 Member States**
*Philippe Brunet, European Commission, Belgium*

**Role and Operations of EMEA within the Enlarged EU**
*Anthony Humphreys, EMEA, UK*

**Phasing-in into EU Regulatory Procedures**
*Milan Smid, State Institute for Drug Control, Czech Republic*

**The Implications of Moving from the EU 15 to EU 25 for Industry - Viewpoint of Innovative Industry**
*Michael Doherty, F. Hoffmann-La Roche Ltd., Switzerland*

**Harmonisation – Accession – Europe; Experiences of a CEE Based Pharmaceutical Company**
*Ales Rotar, Krka Pharmaceuticals, Slovenia*

**10:30 Coffee Break in the Exhibition Area**

**11:00 Session 2**

**CENTRALLY APPROVED PRODUCTS: THE IMPACT OF EU ENLARGEMENT**

**Session Co-chairpersons:**

**Anthony Humphreys, EMEA, UK**

**Anu Tummavuori-Liemann, F. Hoffmann-La Roche Ltd., Switzerland**

*The marketing authorisations of EU Centrally Approved Products will extend to the New Member States upon accession. This has many consequences on a practical level:*

- *What is the impact of the enlarged CPMP evaluation procedures?*
- *How will the new languages be incorporated in the systems?*

**Impact on Operation of CPMP and Related Evaluation Procedures**
*Anthony Humphreys, EMEA, UK*

**Consequences of Extension of Commission Decisions to New Member States**
*Jitka Sabartova, State Institute for Drug Control, Czech Republic*

**Extension of CAPs to 10 New Member States. What is the Impact on Industry?**
*Anu Tummavuori-Liemann, F. Hoffmann-La Roche Ltd., Switzerland*

**12:30 Lunch in the Exhibition Area**

**14:00 Session 3**

**MRP: SMOOTH PHASING-IN 10 NEW EU MEMBER STATES**

**Session Chairperson:**

**Dagmar Stará, State Institute for Drug Control, Slovak Republic**

*The expected accession of 10 additional European countries to the current EU in 2004 represents a challenge for an EU regulatory system, with 10 new competent authorities and pharmaceutical industry from a new region involved. What will the implications be for the mutual recognition procedure? How are all partners - regulators and industry - prepared for the exercise? The current status of experience, based on voluntary preaccession cooperation will be presented by regulators both from the point of view of an acceding country and a member of MRFG. Which challenges can be expected in the period early after accession? A complex view will be presented by the pharmaceutical industry.*
*How to deal with MA applications pending and not finalised before the accession in future new member states? Is the arrangement for upcoming period after accession transparent enough? Outcomes from the PERF discussions will be presented.*

**Preparation and Challenges for Phasing-in of New MSs in MRP in May 2004 - View of a Regulator of an Acceding Country**
*Dagmar Stará, State Institute for Drug Control, Slovak Republic*

**Preparation and Challenges for Phasing-in 10 new MSs in MRP in May 2004 - View of a MRFG Member**
*Truus Janse-de Hoog, Medicines Evaluation Board, The Netherlands*

**MRP: Phasing-in 10 New Member States - Innovative Industry View**
*Kerstin Franzen, EFPIA, Belgium*

**An Acceding Country Industry Perspective - A Point of View of a New Participant in MRP**
*Ales Rotar, Krka Pharmaceuticals, Slovenia*

**Panel Discussion with Generic Industry Representatives**

**15:30 Coffee Break in the Exhibition Area**

**16:00 Session 4**

**GOOD REGULATORY PRACTICE CHALLENGE**

**Session Chairperson:**

**Ludevit Martinec, State Institute for Drug Control, Slovak Republic**

*Regulators and industry representatives will share experiences with the introduction of a quality management system adapted to specific regulatory activities to ensure that users of medicinal products, applicants and regulators are satisfied with opinions, assessment reports, inspections, taking into consideration legal requirements and guidance in order to protect and promote human health. Views from a current EU drug regulatory authority, acceding country national authority and industry. From SOPs to a quality management system. How to assess performance and processes, which indicators to use. Achieving scientific consistency in review process. Predictable and adequate decision making. Acceding countries becoming part of the EU regulatory system. PERF III - benchmarking joint visit programme, focus on dossier assessment and pharmacovigilance. What have we learned about our quality systems? Experience with self-assessment in identification of areas in need of improvement. Communication and transparency in regulatory procedures between key players - industry and competent authorities. Which specific regulatory information should be directed to agencies, to industry and general public.*

**Quality Management System of the Drug Regulatory Authorities of the Acceding Countries**
*Ludevit Martinec, State Institute for Drug Control, Slovak Republic*

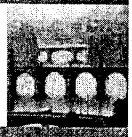
**One Way to Ensure Adequate Quality**
*Tomas Salmonson, Medical Products Agency, Sweden*

**Communication and Transparency between Competent Authorities and Industry**
*Jean-Pierre Osselaere, Schering Plough Europe, Belgium*

**17:30-18:30 Reception in the Exhibition Area**

## EU Enlargement

Dagmar Stará, State Institute for Drug Control, Slovak Republic
Anu Tummavuori-Liemann, F. Hoffmann-La Roche Ltd., Switzerland



FRIDAY, MARCH 12, 2004

**09:00 Session 5**

**MARKET STRUCTURE AND IMPACT ON EXISTING PRODUCTS**

**Session Chairperson:**
**Tamás Paál, National Institute of Pharmacy, Hungary**

*Medicine markets in the acceding countries comprise mostly generics, although there is also access to innovative medicines. The consolidated CADREAC simplified processes for recognition of EU, CP and MRP products have promoted introduction of the latter. Nevertheless, quicker introduction of new innovative medicines is expected. At the same time, EU Commission requires upgrading of old dossiers of all existing products. This has led to a rapid decrease of marketing authorisations. Surprisingly enough, while local companies have been trying their best, many EU-based firms refused to submit upgraded dossiers of their old products on the CEE markets. Its impact on the market and patient access of the first wave, second wave and non-EU candidate European countries should be considered.*

**Public Health and Medicines: A Wider European Perspective**
*Kees de Joncheere, WHO, Denmark*

**Effect of Enlargement from an Acceding Country's Industry Point of View**
*Gyorgy Thaler, Gedeon Richter Ltd., Hungary*

**EU Enlargement - A Global Company View**
*Monica Löfgren, Merck Sharp & Dohme, Belgium*

**10:30 Coffee Break in the Exhibition Area**

**11:00 Session 6**

**THE TREATY OF ACCESSION, SPECIFIC MECHANISM AND DEROGATION PROVISIONS**

**Session Chairperson:**
**Brendan Barnes, EFPIA, Belgium**

*The Accession Treaty introduces a specific mechanism for medicinal products that are put on the market in one of the new Member States of the EU and that, for historical reasons, do not have the same level of patent or Supplementary Protection Certificate (SPC) coverage as available in the current EU 15 Member States. For these products, the patent/SPC holder, or his beneficiary, will be able to invoke the patent or SPC rights against any imports of such products in each concerned EU Member State. This session aims to analyse the content and functioning of the provision as well as its implications for New Member States, Member State of the EU 15 and industry.*

**The View of the New Member States**
*Vesna Koblar, Agency for Medicinal Products, Slovenia*

**The View of the Member States of the Current EU**
*John Lisman, Medicines Evaluation Board, The Netherlands*

**The View of the Pharmaceutical Industry**
*Rachel Thornley, GlaxoSmithKline, UK*

**12:30 Lunch in the Exhibition Area**

**14:00 Session 7**

**CONSEQUENCES OF IMPLEMENTATION OF EU REGULATION ON PROMOTION OF MEDICINAL PRODUCTS**

**Session Chairperson:**
**Alar Irs, State Agency of Medicines, Estonia**

*Pharmaceutical marketing and promotion practice as well as its regulation differ significantly among the current EU Member States. Even greater differences can be seen in accession countries. Accession forces the new Member States to review their current regulation of pharmaceutical advertising and its enforcement. The pharmaceutical industry will probably harmonise its marketing practice in old and new Member States. What are the current differences in promotion of medicinal products in old and new Member States? What experiences has the industry gained in the countries with different forms of regulation (self-regulation of advertising, combined regulation or state-regulated environment)? What might be the possible changes in advertising policy and regulation in the enlarged EU?*

**An Informed Patient Is a Better Patient**
*Marie-Claire Pickaert, EFPIA, Belgium*

**Current Practice of Advertising Regulation in the EU**
*Björn Beerman, Medical Products Agency, Sweden*

**Advertising and Its Regulation in Accession Countries**
*Alar Irs, State Agency of Medicines, Estonia*

**15:30 Coffee Break in the Exhibition Area**

**16:00 Session 8**

**IMPLICATIONS OF EU ENLARGEMENT IN CONDUCTING CLINICAL TRIALS IN EUROPE**

**Session Chairperson:**
**Fergus Sweeney, EMEA, UK**

*EU enlargement and implementation of the Directive 2001/20/EC will take place at the same time - May 2004. The enlargement will create a large research area, with an increasingly harmonised regulatory environment, and 480 million citizens, with many commercial and noncommercial research initiatives. The benefits and challenges in ensuring research quality and efficacy are explored from the perspective of regulators, industry and CROs.*

**Regulator's Perspective of Enlargement and Implementation of the Directive 2001/20/EC**
*Alar Irs, State Agency of Medicines, Estonia*

**The Expected Impact of the EU Enlargement on Clinical Trials - A Clinical Operations Perspective**
*Norbert Szakolczai-Sandor, Omnicare Clinical Research, Hungary*

**Implementation Plans and the Impact on the Conduct of Clinical Trials in the Accession Countries - An Industry Perspective**
*Moira Daniels, AstraZeneca, UK*

**17:30 Close of the 16th Annual EuroMeeting Prague 2004**

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## International Regulatory Issues - Half Track - 4 Sessions

Rolf Bass, BfArM, Germany
Stéphane Callewaert, EFPIA, Belgium

# FRIDAY, MARCH 12, 2004

**08:00 Welcome Coffee and Registration**

**09:00 Session 5**

IMPLEMENTATION OF CTD

**Session Co-chairpersons:**
**Stéphane Callewaert, EFPIA, Belgium**
**Yves Juillet, Les Entreprises du Médicament (LEEM), France**
*Since July 2003, CTD implementation has been compulsory. It may be the origin of some difficulties. Practical information will be given using first submissions experience from regulators and industry speakers in Europe. Specific US summary issues will also be addressed in this session.*

**Implementation of CTD in Europe**
*Christa Wirthumer-Hoche, Federal Ministry of Health and Women, Austria*

**Practical Implementation**
*Céline Melcion, Aventis Pharma, France*

**Integration of Safety Data Discussion (ISS or not ISS?)**
*Michael J. Brennan, Centicor, USA*

**10:30 Coffee Break in the Exhibition Area**

**11:00 Session 6**

eCTD IMPLEMENTATION

**Session Chairperson:**
**Andrew Marr, GlaxoSmithKline Pharmaceuticals, UK**
*eCTD will have become a reality in Europe from June 2003 as optional filing became possible from that date. This session will provide feedback on agency and industry experience to date and also the future direction of eCTD development.*

**The Experience of MEB with Receipt and Review of eCTDs to Date**
*Stan van Belkum, Medicines Evaluation Board, The Netherlands*

**The Experience of an Applicant with Construction and Submission of an eCTD**
*Geoff Williams, Johnson & Johnson Pharmaceutical R&D, UK*

**The Resolution of Current Issues and Future Developments of the eCTD within ICH**
*Gabriele Disselhoff, Merck KG, Germany*

**12:30 Lunch in the Exhibition Area**

**14:00 Session 7**

PARTNERSHIP IN HARMONISATION WITH NON-ICH COUNTRIES/ REGIONS

**Session Chairperson:**
**Jurij Petrin, Pharmaceutical Regulatory Services, Inc., USA**
*Non-ICH countries have been following the development of global drug development harmonisation efforts from the very beginning of ICH. Lately, we have witnessed an increasing acceptance of ICH and incorporation of ICH guidelines into local drug development regulations worldwide, including in countries that are not ICH members. This suggests the fact that ICH has now become the accepted international standard for drug development. Nevertheless, important differences between ICH members and non-ICH countries still exist, and some of them will be highlighted and discussed in this session.*

**Current Status and Issues with Global Acceptance of ICH**
*Jurij Petrin, Pharmaceutical Regulatory Services, Inc., USA*

**Asian Harmonisation and Acceptance of ICH**
*Charunee Krisanaphan, FDA, Thailand*

**The Role of ICH in the New Regulatory Environment in China**
*Ali Harrison, AstraZeneca, UK*

**15:30 Coffee Break in the Exhibition Area**

**16:00 Session 8**

REGIONAL COOPERATION IN THE EU MOVING EAST

**Session Chairperson:**
**Borislav Borissov, Bulgarian Drug Agency, Bulgaria**
*The objective of this session is to look into the countries that are planning to join the EU later on in the future enlargement wave, namely the remaining CADREAC countries after May 1, 2004 (Bulgaria, Romania) and the Balkan Region.*

**Clinical Trials**
*Borislav Borissov, Bulgarian Drug Agency, Bulgaria*

**GCP Inspections**
*Csaba Dobroczky, Ministry of Health, Croatia*

**Industry View**
*Brian Hewitt, Pfizer Ltd., UK*

**17:30 Close of the 16th Annual EuroMeeting Prague 2004**

**Statistics and Data Management**
Joachim Vollmar, PRA International, USA

THURSDAY, MARCH 11, 2004

**08:00 Welcome Coffee and Registration**

**09:00 Session 1**

**ENDPOINTS IN CLINICAL CPMP GUIDELINES: STATISTICAL IMPLICATIONS**
**Session Chairperson:**
**Joachim Röhmel, Federal Institute for Drugs and Medical Devices, Germany**
*During the last 10 years CPMP has approved more than 60 clinical Note-for-Guidance and Points-to-Consider documents. Many of them include strong requirements for clinically meaningful and interpretable endpoints. The consequences of these requirements on the design and statistical analysis are often not fully understood, even among statisticians. Three selected areas will be scrutinized in the session:*
*1. Clinical relevance; 2. Noninferiority; 3. Combined endpoints*

**Assessment of Requirements for the Demonstration of Clinical Relevance in CPMP Guidelines**
*Meinhard Kieser, Schwabe Pharmaceuticals, Germany*

**Combined Endpoints with Components of Different Importance**
*Armin Koch, Federal Institute for Drugs and Medical Devices, Germany*
*Joachim Röhmel, Federal Institute for Drugs and Medical Devices, Germany*

**The Concept of Noninferiority and Noninferiority Margins in the CPMP Clinical Guidelines**
*Stephen Senn, University of Glasgow, UK*

**10:30 Coffee Break in the Exhibition Area**

**11:00 Session 2**

**CURRENT STRATEGIES FOR DEALING WITH MISSING DATA IN CLINICAL TRIALS**
**Session Co-chairpersons:**
**Michael Branson, Novartis Pharma AG, Switzerland**
**Armin Koch, Federal Institute for Drugs and Medical Devices, Germany**
*In most clinical trials we observe, to a greater or lesser extent, missing data. Clinical trials in which some patients have missing responses, or outcome(s), induce potential problems in terms of performing an analysis that reflects appropriately the treatment difference and the confidence with which such differences should be stated. Consequently, clinical interpretation will also be affected. In this session, methods for dealing with missing data in clinical trials will be discussed and approaches outlined that permit differences between treatments to be quantified. Such approaches will also be discussed from a regulatory perspective.*

**Missing Data in Clinical Trials: Moving from Simple Approaches to More Principled Strategies - A Discussion**
*Michael Branson, Novartis Pharma AG, Switzerland*

**Considerations Regarding Choice of the Primary Analysis in Longitudinal Trials with Dropouts: An FDA Perspective**
*Robert O'Neill, FDA, USA*

**Discussion**

**12:30 Lunch in the Exhibition Area**

**14:00 Session 3**

**REPORTING GUIDELINES FOR CLINICAL TRIALS**
**Session Chairperson:**
**Simon Day, MHRA, UK**
*This session will review published reporting guidelines for clinical trials, meta-analyses and studies of diagnostic agents. The usefulness of the guidelines for publication in journals and for license applications will be considered.*

**QUOROM (Guideline for Reporting Meta-Analyses)**
*David Wright, MHRA, UK*

**Guidelines for Reporting Studies of Diagnostic Agents**
*Mike Campbell, University of Sheffield, UK*

**CONSORT (Guideline for Reporting Individual Trials)**
*Stephen J.W. Evans, London School of Hygiene & Tropical Medicine, UK*

**15:30 Coffee Break in the Exhibition Area**

**16:00 Session 4**

**ELECTRONIC TRIALS AND DOCUMENT MANAGEMENT**
**Session Chairperson:**
**Thorkild Nielsen, F. Hoffmann-La Roche Ltd., Switzerland**
*This session will cover the broad topic of e-trials and document management, and the speakers will share their experience and views on management of documents and information from an internal company perspective when interacting with investigators. Ideas on how to extend the use of the Internet and using portals will be presented, as well as further outlooks.*

**Benefits of IntraWeb as a Communication and Collaboration Tool for International Data Management**
*David Townsend, Novo Nordisk A/S, Denmark*

**Managing Communication Challenges between Disparate Teams to Make Sure e-Clinical Trials Work in Practice**
*Graham Bunn, Quintiles, UK*

**Moving Beyond the Portal**
*Ken Youngstein, BIOCOM Ltd., Switzerland*

**17:30-18:30 Reception in the Exhibition Area**

**Statistics and Data Management**
Joachim Vollmar, PRA International, USA

FRIDAY, MARCH 12, 2004

**09:00 Session 5**

**STATISTICAL CONSIDERATIONS IN THE EVALUATION OF PK/PD DATA**

**Session Chairperson:**
**Harry Mager, Bayer AG, Germany**

*Population PK/PD models have recently received a great deal of attention, both in drug development and for the establishment of individualized dosing regimens. Important decisions, including labelling, may be based on these models and, thus, the statistical assumptions they rely on. The session will take a critical look at the assumptions that may slip into the modelling endeavours, for example the normal distribution of errors, provide guidance on diagnostics supporting the detection of influential cases, and will give the opportunity to discuss the potential usefulness of the Bayesian modelling approach in a clinical setting.*

**New Developments in Parametric and Nonparametric Population Modelling**
*Roger Jelliffe, University of Southern California, USA*

**Mixed-effects Modelling of Population Kinetics with Bayesian Estimation of Individual Parameters**
*Ruedi Port, German Cancer Research Center, Germany*

**Testing the Statistical Assumptions in Population PK/PD Analyses**
*Niclas Jonsson, University of Uppsala, Sweden*

**10:30 Coffee Break in the Exhibition Area**

**11:00 Session 6**

**SUCCESSFUL SWITCH TO ELECTRONIC DATA CAPTURE**

**Session Chairperson:**
**Siegbert Kloos, F. Hoffmann-La Roche Ltd., Switzerland**

*This session will focus on the paradigm shift and its consequences when transitioning from paper to electronic CRFs. Special attention will be paid to the magnitude and scope of organisational changes and the critical success factors when implementing EDC on a global scale.*

**EDC at the German Coordination Centres for Clinical Trials (KKS) - State of the Art for Data Management**
*Thomas Bratke, KKS. Germany*

**Critical Success Factors for Global EDC Implementation**
*Ronald Waife, Waife & Associates, Inc., USA*

**Case Report: Global Implementation of EDC in Roche**
*Andrew Monaghan. Roche, UK*

**12:30 Lunch in the Exhibition Area**

**14:00 Session 7**

**STATISTICAL TOOLS TO MANAGE THE PRODUCT DEVELOPMENT PROCESS**

**Session Chairperson:**
**Joachim Vollmar, PRA International, USA**

*The drug development process is an imperfectly predictable process. This is often neglected when applying conventional programme management techniques. The use of different statistical tools and models in product and life cycle management will be discussed in this session featuring speakers with statistical drug development expertise.*

**Study Management: It's All in the Probability Distribution**
*Stephen Jones, Covance, UK*

**Applying Disease Progression Models to Clinical Trials**
*Alan Hochberg, ProSanos Corporation, USA*

**Probability-Cost-Profitability Architecture of Portfolio Management in the Pharmaceutical Industry**
*Andreas Zipfel, Bayer Pharma, France*

**15:30 Coffee Break in the Exhibition Area**

**16:00 Session 8**

**STATISTICAL AND DATA MANAGEMENT ISSUES IN PAEDIATRIC DRUG DEVELOPMENT**

**Session Chairperson:**
**Klaus Rose, Novartis Pharma AG, Switzerland**

*This session will give an update on the state of the art of statistical and methodological challenges in paediatric drug development. It will cover methodological aspects of extrapolation of adult and elder children's data into younger children as well as hands-on experiences of electronic data capturing in paediatric clinical trials.*

**Statistical and Methodological Challenges in Designing Paediatric Drug Development Programmes**
- **Industry Perspective**
  *Amy Racine, Novartis Pharma AG, Switzerland*

**Statistical and Methodological Challenges in Designing Paediatric Drug Development Programmes**
- **Academic Perspective**
  *Wolfgang Koepke, University of Muenster, Germany*

**Electronic Data Capturing in Paediatric Clinical Trials**
*Valdo Arnera, PHT, Switzerland*

**17:30 Close of the 16th Annual EuroMeeting Prague 2004**

## THURSDAY, MARCH 11, 2004

**08:00 Welcome Coffee and Registration**

**09:00 Session 1**

CLINICAL SAFETY IN CLINICAL TRIALS: THE NEW EU DIRECTIVE AND GUIDANCE DOCUMENTS

**Session Chairperson:**
**Birka Lehmann, Belgium**

*The presentations will be focused on the principles and the implementation of the guidance documents relating to clinical safety as viewed by the Commission, the Member States and a company. Some specific challenges will be discussed together with the contribution of the CIOMS VI Working Group dealing with the same topic.*

**Management of Clinical Safety in Clinical Trials According to the EU Directive**
*Birka Lehmann, Belgium*

**The Guidance on Safety Reporting - Toward a European and Worldwide Harmonisation of the Regulatory Requirements**
*Chantal Belorgey, AFSSAPS, France*

**Implementing the EU Clinical Trials Directive Guidance**
*Valerie Salmons, Eli Lilly & Company Ltd., UK*

**Panel Discussion with Marianne Keisu, AstraZeneca R&D, Sweden**

**10:30 Coffee Break in the Exhibition Area**

**11:00 Session 2**

NEW ICH GUIDELINES: ADDENDUM TO E2C, E2D, QT PROLONGATION

**Session Chairperson:**
**Anne Castot, AFSSAPS, France**

*One of the remaining areas for the development of ICH guidelines is pharmacovigilance. After the first E2 series and their implementation in the three ICH regions, there was a need to complement these by further harmonisation of approaches to drug safety. This initiative has resulted in new guidelines: An addendum to ICH E2C (related to Periodic Safety Update Reports). E2D aimed at harmonising definitions and standards during pre- and postapproval periods as well as Good Case Management Practices and E14, which deals specifically with clinical trials aimed at detecting and evaluating the potential of new compounds to prolong QT/QTc interval and induce torsade de pointes.*

**The Addendum to ICH E2C Guidelines: For a Better Preparation of Periodic Safety Update Reports (PSURs)**
*Anne Castot, AFSSAPS, France*

**ICH-E2D: Postapproval Safety Data Management**
*Alain Micaleff, Serono, Switzerland*

**Postmarketing Evaluation of Torsadogenic Risk and Its Management**
*Yasmin Shah, MHRA, UK*

**Panel Discussion with Thierry Nebout, IRIS, France**

**12:30 Lunch in the Exhibition Area**

**14:00 Session 3**

THE PHARMACOVIGILANCE AT THE EMEA: EUDRAVIGILANCE AND OTHER INITIATIVES

**Session Chairperson:**
**Panos Tsintis, EMEA, UK**

*This session will describe the organisation of the pharmacovigilance sector at the European Agency for the Evaluation of Medicinal Products, the activities and the current status of EudraVigilance database and its use in pharmacovigilance, the collaboration with the competent authorities of the Member States and finally a company experience of the electronic transmission of Individual Case Safety Reports.*

**Safety Data Handling at the EMEA: Roles, Responsibilities and Procedures**
*Panos Tsintis, EMEA, UK*

**EudraVigilance System:**
**Pre- and Postmarketing Safety Data Management**
*Sabine Brosch, EMEA, UK*

**Electronic Transmission of Individual Case Safety Reports by a Company to the EMEA**
*David Lewis, GlaxoSmithKline, UK*

**Panel Discussion with Bernd Eberwein, Bundesverband der Arzneimittel-Hersteller, Germany**

**15:30 Coffee Break in the Exhibition Area**

**16:00 Session 4**

INTERNATIONAL HARMONISATION OF THE ELECTRONIC TRANSMISSION OF INDIVIDUAL CASE SAFETY REPORTS: ICH E2BM IMPLEMENTATION WORKING GROUP

**Session Co-chairpersons:**
**Sabine Brosch, EMEA, UK**
**Gaby Danan, Aventis Pharma, France**

*In February 2003 a new Implementation Working Group (IWG) was created in ICH to facilitate through the publication of questions and answers received from the users of the harmonisation of the electronic transmission of the Individual Case Safety Reports according to E2BM guideline and M2 specification. This session will describe the remit and activities of this IWG, including the cooperation with MedDRA "Points to Consider" and M2 working groups and will provide an update of the situation in the US and Japan.*

**The Activities of the ICH E2BM IWG and the Situation of the Electronic Transmission of ICSRs in the EU**
*Sabine Brosch, EMEA, UK*

**US Perspective on the Electronic Transmission of Individual Case Safety Reports Using the ICH E2BM Standard**
*William Gregory, Pfizer Inc., USA*

**The Situation of the Electronic Transmission of ICSRs in Japan**
*Shinsuke Yamanobe, Pfizer Pharmaceuticals Inc., Japan*

**17:30-18:30 Reception in the Exhibition Area**

## FRIDAY, MARCH 12, 2004

**09:00 Session 5**

PHARMACOVIGILANCE IN THE ACCESSION MEMBER STATES

**Session Chairperson:**
**Jan Petracek, State Institute for Drug Control, Czech Republic**

*Accession countries have their own culture, history and practices of ADR monitoring. This session should address the impact of EU harmonised legislation on existing day-to-day practices, including emerging technical and ethical questions in the area of pharmacovigilance.*

**Meeting Accession Challenges in the Pharmacovigilance Area**
*Jan Petracek, State Institute for Drug Control, Czech Republic*

**Pharmacovigilance Unit in a CEEC Drug Regulatory Agency**
*Pavol Gbelec, State Institute for Drug Control, Slovak Republic*

**Ethics and Pharmacovigilance in Postmarketing Safety Studies**
*Mateja Marcun, Pharmacovigilance Centre, Slovenia*

**10:30 Coffee Break in the Exhibition Area**

**11:00 Session 6**

RISK MANAGEMENT: VARIOUS APPROACHES

**Session Co-chairpersons:**
**Barry Arnold, AstraZeneca, UK**
**Noël Wathion, EMEA, UK**

*This session will review the need for improved patient risk management activities in Europe and then cover aspects relating to ongoing pre- and post-marketing risk management initiatives.*

**Evaluating Evidence of Safety**
*Saad Shakir, Drug Safety Research Unit, UK*

**Premarketing Pharmacovigilance in the Future: Impact of Recent Initiatives**
*Sabine Eberlein-Stoodt, Covidence GmbH, Germany*

**Postmarketing Risk Management Activities**
*Jon Price, MHRA, UK*

**With the participation of Noël Wathion, EMEA, UK**

**12:30 Lunch in the Exhibition Area**

**14:00 Session 7**

COMPLIANCE IN PHARMACOVIGILANCE AND INSPECTIONS

**Session Chairperson:**
**Gaby Danan, Aventis Pharma, France**

*Within the framework of compliance with the pharmacovigilance obligations, more and more attention is being paid by the competent authorities to pharmacovigilance systems developed by companies. Although their ability to document and report adverse events is under scrutiny, all of the processes and procedures to ensure good pharmacovigilance i.e. detection, evaluation, assessment and prevention of drug safety issues are being carefully inspected. What do the companies need to know to be successfully inspected? This session will give attendees the opportunity to learn from and discuss with experts from Member States and companies their experience of inspections.*

**PMS Inspections: Is "Zero Tolerance" Effective?**
*Bruno Stricker, IGZ, The Netherlands*

**The Reality of Inspections in Europe**
*Vicky Edwards, AstraZeneca, UK*

**Pharmacovigilance Inspections: Recent Lessons Learned**
*Maria Koster, Vigilex BV, The Netherlands*

**15:30 Coffee Break in the Exhibition Area**

**16:00 Session 8**

GOOD PHARMACOVIGILANCE PRACTICES

**Session Chairperson:**
**Carmen Kreft-Jais, AFSSAPS, France**

*Good Pharmacovigilance Practices are being written in the EU and in the US and will be the reference documents for audits and inspections. This session will describe the latest developments in this area by the most involved regulators and the members of the industry.*

**Introductory Remarks**
*Carmen Kreft-Jais, AFSSAPS, France*

**Good Pharmacovigilance Practices - A Perspective from the Pharmacovigilance Working Party**
*Dolores Montero, Spanish Medicines Agency, Spain*

**How to Improve Data Quality in Pharmacovigilance**
*Stephen Douglas, Parexel International Ltd., UK*

**Good Pharmacovigilance Practices - A Perspective from the US**
*Bruce Bush, Johnson & Johnson Pharmaceuticals, USA*

**17:30 Close of the 16th Annual EuroMeeting Prague 2004**

## THURSDAY, MARCH 11, 2004

**08:00 Welcome Coffee and Registration**

**09:00 Session 1**

### SAFETY PHARMACOLOGY: ICH UPDATE AND NEW APPROACHES

**Session Co-chairpersons:**
**Gerd Bode, Altana Pharma, Germany**
**Andrew Sullivan, GlaxoSmithKline, UK**

*Safety pharmacology is a rapidly evolving area of nonclinical safety testing, and an area of particular interest at present is assessment of the effect of compounds on cardiac repolarisation. The first presentation in this session will provide an update of both the nonclinical (S7B) and the clinical (E14) guidelines being written under the ICH process. This will be followed by a discussion of recently available data in this area. Finally, there will be a presentation of new methodology that has the potential to predict the ability of a compound to cause cardiac arrhythmias rather than just QT interval prolongation.*

**Regulatory Update on S7B and Its Impact on E14**
*Klaus Oleinczak, BfArM, Germany*

**A Review of New Data on QT**
*Tim Hammond, AstraZeneca, UK*

**Is Action Potential Prolongation Always Proarrhythmic?**
*Luc Hondeghem, HPC nv, Belgium*

**10:30 Coffee Break in the Exhibition Area**

**11:00 Session 2**

### IMMUNOTOXICOLOGY: ICH UPDATE AND TRICKY ISSUES

**Session Chairperson:**
**Steven Spanhaak, Johnson & Johnson Pharmaceutical R&D, Belgium**

*This session aims to give insight into the different standpoints regarding the response on the recently performed ICH immunotoxicology survey. Regulatory, industrial and academic points of view will be presented.*

**A Regulator's View of the ICH Survey Response and the Way Forward in the EU**
*Jan Willem van der Laan, Medicines Evaluation Board, The Netherlands*

**The ICH Survey Response: The Industrial Point of View**
*Jennifer Sims, Novartis Pharma AG, Switzerland*

**The ICH Survey Response: An Academic Point of View**
*Kimber White, Virginia Commonwealth University, USA*

**Panel Discussion with Ken Hastings, FDA, USA**

**12:30 Lunch in the Exhibition Area**

**14:00 Session 3**

### JUVENILE ANIMAL TOXICITY TESTING OF DRUGS INTENDED FOR THE TREATMENT OF CHILDREN

**Session Chairperson:**
**Bengt Danielsson, AstraZeneca, Sweden**

*This session will review the FDA guidance for nonclinical studies to support paediatric indications and allow the opportunity to hear the European view on juvenile toxicity studies. An industry speaker will discuss the implications of the available guidance for industry and practical considerations when conducting juvenile animal studies.*

**Overview of US FDA Guidance for Juvenile Toxicity Studies**
*Kenneth Hastings, FDA, USA*

**European View on Nonclinical Safety Evaluation of Paediatric Drug Products**
*David Jones, MHRA, UK*

**Considerations When Undertaking Juvenile Animal Studies: Implications for the Industry**
*Mark Hurtt, Pfizer, USA*

**15:30 Coffee Break in the Exhibition Area**

**16:00 Session 4**

### FIRST-TIME-IN-MAN STUDIES USING BIOMARKER APPROACHES: WHAT DOES THE CLINICIAN EXPECT FROM THE TOXICOLOGIST?

**Session Chairperson:**
**Phil Wilcox, GlaxoSmithKline, UK**

*This session will discuss the growing interest in conducting early single-dose pharmacology studies in man to aid the selection of drug candidates with optimal properties based on pharmacokinetic or pharmacodynamic endpoints. Barriers to conducting such studies will be addressed, including the supporting preclinical toxicology package. The discussion will focus on the value of such studies in selecting/developing better medicines and whether abbreviated toxicology packages could be designed that would facilitate the conduct of such studies whilst providing appropriate reassurance of safety for the volunteers/patients involved.*

**Utility and Safety of Single-dose Clinical Studies of New Chemical Entities**
*Bob Holland, AstraZeneca, UK*

**Preclinical Approaches to Support Early Single-dose Clinical Studies**
*Phil Wilcox, GlaxoSmithKline, UK*

**Clinical Interpretation of Nonclinical Data: Is Regulatory Oversight Simply One of Addressing the Guidelines?**
*Philip Harrison, MHRA, UK*

**17:30-18:30 Reception in the Exhibition Area**

FRIDAY, MARCH 12, 2004

**08:00 Welcome Coffee and Registration**

**09:00 Session 5**

**(Joint Session with Track 1 Session 5)**

IMMUNOGENICITY OF BIOTECHNOLOGY-DERIVED THERAPEUTIC PRODUCTS

**Session Chairperson:**

**Iman Barilero, Johnson & Johnson Pharmaceutical R&D, UK**

*The majority of biotechnology-derived therapeutic products exhibit some level of immunogenicity, with clinical sequelae that vary from having no adverse clinical consequences to severe adverse events, depending on the product and its indication. The investigation of immunogenicity is evaluated by measuring levels of specific antiproduct antibodies. However, results are wholly dependent on the design and the analysis of the assay. The aim of this session is to explore the safety problems associated with immunogenicity, to address some considerations in designing studies to investigate immunogenicity, and to provide some insight into current regulatory decision making on immunogenicity testing, a risk-based approach. A target risk-assessment, product/specific pharmacovigilance management plan will be discussed. Representatives from industry, FDA, EMEA and Member States will provide their views and experiences on this important issue.*

**Preclinical and Clinical Considerations**
*Cindy Wang, Medical Products Agency, Sweden*

**Current Regulatory Decision Making on Immunogenicity Testing - A Risk-based Approach?**
*Anthony Mire-Sluis, FDA/CDER, USA*

**Postmarketing Surveillance and Risk Management**
*John Knight, Johnson & Johnson Pharmaceutical R&D, USA*

**Panel Discussion with Pekka Kurki, National Agency for Medicines, Finland**

**10:30 Coffee Break in the Exhibition Area**

**11:00 Session 6**

QUALITY ASPECTS OF TOXICOLOGY STUDIES: THE MINIMISATION OF DRUG IN CONTROL SAMPLES

**Session Chairperson:**

**David Kirkland, Covance, UK**

*The CPMP Position Paper intends to give guidance to industry on the need to assay the levels of test substance in the samples from controls in the most relevant toxicology studies, on reporting the findings and on assessing the impact of any putative "controls contamination" on the validity of the studies. A workshop organised by EFPIA in October 2003 brought together senior toxicologists and bioanalytical experts with the objective of reaching a consensus on minimisation of the detection of drugs in biological samples from control animals in toxicology studies. The outcome of this workshop will be presented.*

**CPMP Position Paper on Contamination of Control Samples in Toxicology Studies**
*Beatriz Silva Lima, University of Lisbon, Portugal*

**Feedback from Industry Workshop: Best Practices in the Conduct of Toxicology Studies**
*Tim Gray, Sanofi-Synthelabo, UK*

**Feedback from Industry Workshop: Best Practices in the Toxicokinetic and Bioanalytical Aspects of Toxicology Studies**
*Susan Fowles, GlaxoSmithKline, UK*

**12:30 Lunch in the Exhibition Area**

## Quality Issues and Manufacturing - Half Track - 4 Sessions

Stuart Heir, Novartis Pharma AG, Switzerland
Rolf Spang, Swissmedic, Switzerland

## FRIDAY, MARCH 12, 2004

**08:00 Welcome Coffee and Registration**

**09:00 Session 5**

QUALITY GUIDELINES UPDATE

**Session Chairperson:**
**Jean-Louis Robert, Laboratoire National de la Santé, Luxembourg**
*The session will give an update on recent developments in the pharmaceutical quality area with special emphasis on pharmaceutical development and risk-based approach, including the chemical and pharmaceutical industry.*

**Quality Topics**
*Jean-Louis Robert, Laboratoire National de la Santé, Luxembourg*

**Viewpoint of the Chemical Industry**
*Lothar Hartmann, F. Hoffmann-La Roche Ltd., Switzerland (CEFIC/APIC Representative)*

**Viewpoint of the Pharmaceutical Industry**
*Fritz Eini, Novartis Pharma AG, Switzerland*

**10:30 Coffee Break in the Exhibition Area**

**11:00 Session 6**

MUTUAL RECOGNITION AGREEMENT

**Session Chairperson:**
**Susanne Braunhofer, Novartis Pharma AG, Switzerland**
*This session describes the implications of MRA in relation to EU batch release strategy, implementation at industry, EU regulations and the impact on EU accession countries.*
*They have a big impact on company release strategy, avoidance of redundant analytical work and complex supply chains.*
*Status of other MRAs.*

**MRA and EU Batch Release - Implementation in Industry**
*Susanne Braunhofer, Novartis Pharma AG, Switzerland*

**Experience with MRAs from an Industry Point of View**
*Juergen Knoebel, F. Hoffmann-La Roche Ltd., Switzerland*

**MRA from a Regulatory Point of View**
*Beatrice Oberle Rolle, Novartis Pharma AG, Switzerland*

**12:30 Lunch in the Exhibition Area**

**14:00 Session 7**

GMP INSPECTIONS

**Session Chairperson:**
**Emer Cooke, EMEA, UK**
*This session will explore the relationship between the information provided from a GMP perspective and the information provided in the quality part of the dossier and look at the potential benefits of enhancing this cooperation. It is anticipated that elements from the ICH discussions on GMP for the 21st century will be addressed, particularly in the context of facilitating the introduction of innovative new technologies.*

**The Pharmaceutical Development Report as Tool for GMP Inspections**
*Emer Cooke, EMEA, UK*

**Approaches to New Technologies, the Role of the GMP Inspector vs. the Role of the Quality Assessor**
*Gordon Munro, MHRA, UK*

**Challenges for the Company - Manufacturing vs. Regulatory Affairs**
*Neil Wilkinson, AstraZeneca, USA*

**15:30 Coffee Break in the Exhibition Area**

**16:00 Session 8**

EU CERTIFICATION

**Session Chairperson:**
**Katrina McLoughlin, GlaxoSmithKline R&D, UK**
*The area of "quality" certification is an increasingly varied one - this session will review what is available from drug product through to drug substance, as well as highlighting the broader relevance of such certification around the globe.*

**The WHO Certification Scheme and Activities**
*Lembit Rägo, WHO, Switzerland*

**The European Situation**
*Emer Cooke, EMEA, UK*

**International Aspects**
*Katrina McLoughlin, GlaxoSmithKline R&D, UK*

**17:30 Close of the 16th Annual EuroMeeting Prague 2004**

**Medical Devices - Half Track - 4 Sessions**
Martine Delétraz-Delporte, Faculty of Pharmacy of Grenoble, France
Roger Grase, BfArM, Germany

FRIDAY, MARCH 12, 2004

**08:00 Welcome Coffee and Registration**

**09:00 Session 5**

**CLASSIFICATION OF DEVICES IN THE EU**

**Session Chairperson:**
**Martine Delétraz-Delporte, Faculty of Pharmacy of Grenoble, France**

*Borders between medicinal products and devices are not well defined in many cases. It is different from one region to another, and implementation of European regulations may be not totally coherent in the Member States. Due to these difficulties it is not always easy for companies to make good choices and consider the classification of their products, particularly for medical devices. Answers are to be found in theory in the European Directives and guidelines, but in practice the answers are sometimes difficult to find. In the session the current regulations will be described and practical examples of implementation will be given with some information on how the difficulties have been addressed.*

**European Directives and Borderline Products: Basic Data**
*Martine Delétraz-Delporte, Faculty of Pharmacy of Grenoble, France*

**Directives Implementation: Classification of MD**
*Johann Rader, TÜV, Germany*

**Directives Implementation: Propositions of Modifications**
*Stéphane Laroche, Lab Becton Dickinson, France*

**10:30 Coffee Break in the Exhibition Area**

**11:00 Session 6**

**THE REGULATION OF DEVICE/DRUG COMBINATION PRODUCTS AN INTERNATIONAL COMPARISON**

**Session Chairperson:**
**Roger Grase, Federal Institute for Drugs and Medical Devices, Germany**

*Device/drug combination products are the newest challenge of the pharmaceutical and medical devices sector. The increasing importance is also based on recent advances in technology. An overview on the regulations of medical devices is given. This session is of interest to both medical devices and pharmaceutical sector representatives.*

**The Regulation of Combination Products in Canada - Recent Experiences**
*Karolyn Lui, Health Canada, Canada*

**The Consultation Procedure for Combination Products in the EU**
*Roger Grase, Federal Institute for Drugs and Medical Devices, Germany*

**The Review of Drug-Device Combinations in the EU - An Industry Perspective**
*Julian Britton, Wyeth Research, UK*

**12:30 Lunch in the Exhibition Area**

**14:00 Session 7**

**REGULATORY, CLINICAL AND STATISTICAL CONSIDERATIONS IN EVALUATING MEDICAL DEVICES**

**Session Chairperson:**
**Joachim Schwarz, Quintiles GmbH, Germany**

*Overview of regulatory requirements for the clinical development of medical devices (MDs), including in vitro diagnostic devices (IVDMDs) in Europe, the legal prerequisites and requirements for clinical trials and statistical considerations, including sample size aspects. Relevant differences between Europe and the USA will be addressed to comply with both legislations and to avoid redundant work when developing MDs and IVDMDs.*

**Clinical Trial Regulatory EU vs. USA**
*Gerd Juhl, Quintiles Consulting, Germany*

**Requirements for Clinical Trials with Medical Devices (including IVDs)**
*Joachim Schwarz, Quintiles GmbH, Germany*

**Statistical Considerations EU vs. USA**
*Joachim Röhmel, Federal Institute for Drugs and Medical Devices, Germany*

**15:30 Coffee Break in the Exhibition Area**

**16:00 Session 8**

**ADVERSE INCIDENT - VIGILANCE AND USER REPORTING**

**Session Chairperson:**
**David Jefferys, MHRA, UK**

*This session will review recent developments in vigilance reporting for medical devices across Europe and internationally through the Global Harmonisation Task Force. It will also consider important recent developments on the handling of medical device/user errors and the importance of designing for patient safety.*

**Vigilance and User Reporting in the UK**
*David Jefferys, MHRA, UK*

**GHTF Global Aspects**
*Rainer Voelksen, Swissmedic, Switzerland*

**Industry Perspective**
*Roland Gerard, St. Jude Medical Europe, Inc., Belgium*

**17:30 Close of the 16th Annual EuroMeeting Prague 2004**

# 16TH ANNUAL EUROMEETING

## Wednesday, March 10, 2004

| | |
|---|---|
| 09:00-12:30 | |
| 14:00-17:15 | |
| 17:15-18:00 | DISTINGUISHED CAREER AND OUTSTANDING SERVI |
| 18:00-21:00 | |

## Thursday, March 11, 2004

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|---|---|---|---|---|---|---|---|
| 08:00-09:00 | WELCOME COFFEE - REGI | | | | | | |
| | **Track 1** | **Track 2** | **Track 3** | **Track 4** | **Track 5** | **Track 6** | **Track 7** |
| | **Drug Discovery and New Technologies** | **Clinical Trials and Therapeutic Areas** | **Project Management and Outsourcing** | **EU Regulatory Environment** | **EU Enlargement** | **International Regulatory Issues** | **Statistics and Data Management** |
| 09:00 Session 1 | Genetics and Personlised Medicine, Managing Drug Development in the Post-Genomic Era | CNS and Neuropathic Pain Guidelines | Sessions 1 & 2 Combined Competency Mapping and Developing High-performance Teams | Centralised Procedure - The Role of Therapeutic Advisory Groups (TAG) | Regulatory Implications: From 15 to 25 Member States | | Endpoints in Clinical CPMP Guidelines: Statistical Implications |
| 10:30 | COFFEE BREA | | | | | | |
| 11:00 Session 2 | Pharmacogenomic-Guided Drug Development: Regulatory and Research Policy Perspectives | Should New Data Change the Osteoporosis Guideline? (HRT - Duration of CTS) | Sessions 1 & 2 Combined Competency Mapping and Developing High-performance Teams | Key Elements in the Regulation of the New European Medicines Legislation | Centrally Approved Products: The Impact of EU Enlargement | | Current Strategies for Dealing with Missing Data in Clinical Trials |
| 12:30 | LUNCH II | | | | | | |
| 14:00 Session 3 | Ensuring Diagnostic Standards for Genetically-Informed Drug Development | European Directive on Clinical Trials: Current Implementation Status in the 15 Member States and in the Industry - Part I - Ethical Issues | The Present and Future Shape of Project Management in Pharma R&D | CPMP Scientific Advice and Protocol Assistance | MRP: Smooth Phasing-in of 10 New EU Member States | | Reporting Guidelines for Clinical Trials |
| 15:30 | COFFEE BREA | | | | | | |
| 16:00 Session 4 | Comparability of Biotechnological/Biological Products | European Directive on Clinical Trials: Current Implementation Status in the 15 Member States and in the Industry - Part II | Knowledge Management for Clinical Teams: Identifying Training Needs | Key Elements in the Directive 2001/83/EC - Non Centrally Approved Products | Good Regulatory Practice Challenge | | Electronic Trials and Document Management |
| 17:30-18:30 | RECEPTION | | | | | | |

## Friday, March 12, 2004

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|---|---|---|---|---|---|---|---|
| 09:00 Session 5 | (Joint Session with Track 9, Session 5) Immunogenicity of Biotechnology-Derived Therapeutic Products | Compliance with GCP | Project Planner: A New Role on the Project Team | Referrals - Which Way Now? | Market Structure and Impact on Existing Products | Implementation of CTD | Statistical Consideration in the Evaluation of PK/PD Data |
| 10:30 | COFFEE BREA | | | | | | |
| 11:00 Session 6 | Biosimilar Medicinal Products | Development of Oncology Products (Part I) | Project Management Outside Product Development | Regulatory Data Protection | The Treaty of Accession, Specific Mechanism and Derogation Provisions | e-CTD Implementation | Successful Switch to Electronic Data Capture |
| 12:30 | LUNCH II | | | | | | |
| 14:00 Session 7 | Gene Therapy | Development of Oncology Products (Part II) | Project Management in the "New EU" - Central Eastern Europe | Variations | Consequences of Implementation of EU Regulation on Promotion of Medicinal Products | Partnership in Harmonisation with Non-ICH Countries/ Regions | Statistical Tools to Manage the Product Development Process |
| 15:30 | COFFEE BREA | | | | | | |
| 16:00 Session 8 | Cell Therapy | Telematics | Outsourcing Strategies of Selecting a CRAO | Transparency in European Procedures | Implications of EU Enlargement in Conducting Clinical Trials in Europe | Regional Cooperation in the EU Moving East | Statistical and Data Management Issues in Paediatric Drug Development |
| 17:30 | CLOSE OF THE 16TH A | | | | | | |

# PRAGUE 2004 AT A GLANCE

**TIONAL TUTORIALS**
**LENARY SESSIONS**
**E AWARDS CEREMONY / BLACK AND WHITE THEATRE PERFORMANCE**
**UFFET RECEPTION**

**TRATION AND OPENING OF THE EXHIBITION**

| Track 8 | Track 9 | Track 10 | Track 11 | Track 12 | Track 13 | Track 14 | Track 15 |
|---|---|---|---|---|---|---|---|
| Clinical Safety and Pharmacovigilance | Emerging Nonclinical Issues | Quality Issues and Manufacturing | **Medical Devices** | **Public Policy and Patient Access to Medicines in Europe** | **Public Health, Patient Needs and Orphan Drugs** | OTC/SM and Herbal Products Generic Medicinal Products | **Special Populations** |
| Clinical Safety in Clinical Trials: The New EU Directive and Guidance Documents | Safety Pharmacology: ICH Update and New Approaches | | | Collaboration between "Health Technology Assessment" and Industry: A Way Forward | Patients, Science and Industry: A European Way of Promoting Research and Raising Awareness Together | Future Legislative Framework for NonPrescription Medicines | Drug Development in Pregnancy |

**K IN THE EXHIBITION AREA**

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| lew ICH Guidelines: Addendum o E2C; E2D; QT Prolongation | Immunotoxicology: ICH Update and Tricky Issues | | | The Changing Economical Environment for Pharmaceutical Innovation and New Trends in Reimbursement Policies | from Concept to Therapy: The Influence of Patient Groups in the Research Agenda | Future Legislative Framework for Herbal Medicinal Products | Better Medicines for Children: Not an Easy Road |

**THE EXHIBITION AREA**

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|---|---|---|---|---|---|---|---|
| The Pharmacovigilance at the MEA: EudraVigilance and other Initiatives | Animal Juvenile Toxicity Testing of Drugs Intended for the Treatment of Children | | | Medicines Evaluation in the Real-Life Setting | The Challenge of Guiden Standards: Clinical Trials for Rare Diseases, a Public Health Perspective | Scientific Assessment of Medicinal Plants | Drug Development in the Aging Population |

**K IN THE EXHIBITION AREA**

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|---|---|---|---|---|---|---|---|
| nternational Harmonisation of he Electronic Transmission of ndividual Case Safety Reports: ICH E2BM Implementation Working Group | First-time-in-man Studies Using Biomarker Approaches: What Does the Clinician Expect from the Toxicologist? | | | EU Enlargement and Product Diversion: How to Meet the Needs of Public Health | Policy Continuity in Orphan Drugs: From Concept to Patients | Food Supplements and Borderline between Medicines and Food | Ethical Issues in Studies with Vulnerable Populations |

**IN THE EXHIBITION AREA**

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|---|---|---|---|---|---|---|---|
| Pharmacovigilance in the Accession Member States | (Joint Session with Track 1 Session 5) Immunogenicity of Biotechnology-derived Therapeutic Products | Quality Guidelines Update | Classification of Devices in the EU | | Should Patients Have a Voice in the European Health Agenda? | Generics and the Future Medicines Legislation | |

**K IN THE EXHIBITION AREA**

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|---|---|---|---|---|---|---|---|
| Risk Management: Various Approaches | Quality Aspects of Toxicology Studies: The Minimisation of Drug in Control Samples | Mutual Recognition Agreement | The Regulation of Device/Drug Combination Products An International Comparison | | Access to Medicines in Developing Countries | Implementation of Harmonised SmPCs: Policies and Strategies | |

**THE EXHIBITION AREA**

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|---|---|---|---|---|---|---|---|
| mpliance in Pharmacovigilance and Inspections | | GMP Inspections | Regulatory, Clinical and Statistical Considerations in Evaluating Medical Devices | | Ignored or Informed: What Should Patients Know? | Generics and EU Enlargement | |

**K IN THE EXHIBITION AREA**

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|---|---|---|---|---|---|---|---|
| Good Pharmacovigilance Practices | | EU Certification | Adverse Incident - Vigilance and User Reporting | | Serving the Public's Health: Health Literacy and MedGuides | Generics: Impact on Public Health Systems and Innovation | |

**INUAL EUROMEETING PRAGUE 2004**



THURSDAY, MARCH 11, 2004

**08:00 Welcome Coffee and Registration**

**09:00 Session 1**

**COLLABORATION BETWEEN "HEALTH TECHNOLOGY ASSESSMENT" AND INDUSTRY: A WAY FORWARD**

**Session Chairperson:**
**Rod Taylor, University of Birmingham, School of Public Health, UK**
*Health Technology Assessment (HTA), and particularly its focus on cost effectiveness, has been seen by the healthcare industry as an unwelcome addition to the traditional licensing requirements of quality, safety and efficacy - the so-called "fourth hurdle." This session will discuss some of the current key initiatives of interaction between HTA and the healthcare industry across Europe and also explore possibilities for future collaboration.*

**Balancing Clinical and Cost Effectiveness: The NICE Experience**
*David Barnett, University of Leicester, UK*

**How Can We Foster Synergism? A Conceptual Model for Transparent "Rules of the Game" Based on a Systematic Assessment of Health Technologies, Outcomes Research, and Fair Technological Competitiveness**
*José Antonio Valverde, AETSA, Spain*

**HTA - Industry Collaboration: Thinking Out of the Box**
*Brigitte Casteels, Kyphon, Belgium*

**10:30 Coffee Break in the Exhibition Area**

**11:00 Session 2**

**THE CHANGING ECONOMIC ENVIRONMENT FOR PHARMACEUTICAL INNOVATION AND NEW TRENDS IN REIMBURSEMENT POLICIES**

**Session Chairperson:**
**François Meyer, AFSSAPS, France**
*Trends in drug development costs, risks, and returns will be described and discussed. In light of these trends, the potential from changes of new pharmaceutical pricing and reimbursement policies in Europe will also be examined.*

**Trends in New Drug Development - Costs, Risks and Returns**
*Stuart Walker, CMR International, UK*

**Trends in Pharmaceutical Pricing and Reimbursement in Europe**
*Robert Geursen, Geursen Consulting, Germany*

**Medical Evaluation in the New Transparency Committee in France**
*Jean-Michel Hotton, Pfizer, France*

**12:30 Lunch in the Exhibition Area**

**14:00 Session 3**

**MEDICINES EVALUATION IN THE REAL-LIFE SETTING**

**Session Chairperson:**
**Robert Jones, Association of the British Pharmaceutical Industry, UK**
*Through discussion of the work of NICE in the UK since its first guidance was issued in 2000, this session will explore approaches to the real-life evaluation of medicines. It will review the objectives and methodology of NICE, and discuss the UK health service context within which it works. The evolving relation of NICE with the pharmaceutical industry will also be explored.*

**The Context of NICE's Activities**
*David Barnett, University of Leicester, UK*

**NICE Methodology**
*Carole Longson, National Institute for Clinical Excellence (NICE), UK*

**Health Technology Assessment - Its Scope and Limits**
*Robert Jones, Association of the British Pharmaceutical Industry, UK*

**15:30 Coffee Break in the Exhibition Area**

**16:00 Session 4**

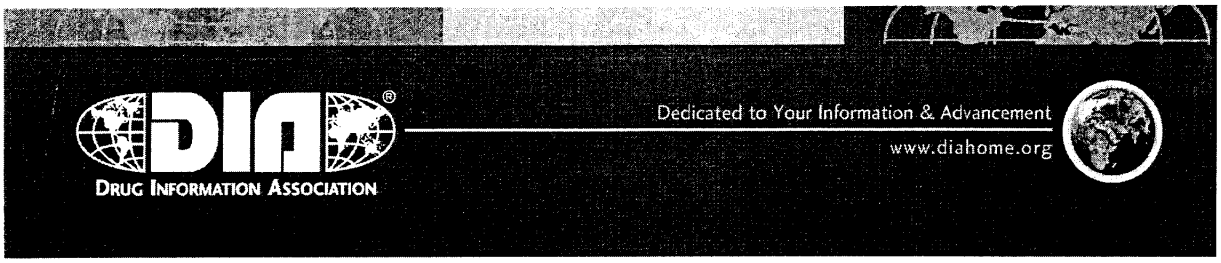
**EU ENLARGEMENT AND PRODUCT DIVERSION: HOW TO MEET THE NEEDS OF PUBLIC HEALTH**

**Session Chairperson:**
**Frances Charlesworth, AstraZeneca, UK**
*There are significant differences in healthcare provision between existing and new member states. This session will describe why innovative medicines are particularly important in countries with limited healthcare resources. The role of accession country governments in ensuring that patients have access to modern medicines will be examined, as will the role of the European Commission in ensuring that strict adherence to free movement of goods does not jeopardise the chances of new and effective treatments being available in the new member states.*

**The Use of Innovative Medicines in the Accession Countries: Medical Necessity and Financial Limitations**
*Sandor Kerpel-Fronius, Semmelweis University of Budapest, Hungary*

**The Case for Market Segmentation in the Interest of Public Health**
*Dermot Glynn, European Economic Research Ltd., UK*

**17:30-18:30 Reception in the Exhibition Area**




# UPCOMING DIA EUROPEAN EVENTS

## MARCH - NOVEMBER 2004

This calendar contains a listing of the DIA events currently scheduled. Complete programmes are generally available three months prior to the event. If you are interested in receiving programme information for an event, please do not hesitate to contact your nearest DIA office. More workshops and educational seminars being planned, watch for the announcements. All programmes are posted on our Web Page www.diahome.org which is regularly updated.

**MARCH 15-16, 2004**
**APPLIED EPIDEMIOLOGY TRAINING COURSE**
HOTEL CROWNE PLAZA AMSTERDAM CITY CENTRE, AMSTERDAM, THE NETHERLANDS

**APRIL 19-21, 2004**
**15TH INTERNATIONAL WORKSHOP ON STATISTICAL METHODOLOGY IN CLINICAL R&D**
THE BURLINGTON HOTEL, DUBLIN, IRELAND

**APRIL 21, 2004**
**A HALF DAY SURVIVAL COURSE IN STATISTICS FOR GENOMIC DATA**
THE BURLINGTON HOTEL, DUBLIN, IRELAND

**APRIL 22-23, 2004**
**4TH INTERNATIONAL WORKSHOP ON STATISTICAL METHODOLOGY IN NON-CLINICAL R&D**
THE BURLINGTON HOTEL, DUBLIN, IRELAND

**APRIL 26-29, 2004**
**SPECIAL TRAINING COURSE ON**
**US REGULATORY AFFAIRS**
**PHASE I - IND PHASE**
**PHASE II - NDA PHASE INCLUDING CTD**
HEIDELBERG MARRIOTT HOTEL, HEIDELBERG, GERMANY

**MAY 10-11, 2004**
**ASSESSING TREATMENT IMPACT USING PRO : CHALLENGES IN STUDY DESIGN, CONDUCT AND ANALYSIS**
HOTEL SOFITEL PARIS FORUM RIVE GAUCHE, PARIS, FRANCE

**JUNE 7, 2004**
**TRAINING COURSE ON EUROPEAN REGULATORY AFFAIRS**
SCANDIC HOTEL COPENHAGEN, COPENHAGEN, DENMARK

**SEPTEMBER 28-30, 2004**
**MIDDLE EAST REGULATORY CONFERENCE MERC 6**
DUBAI, U.A.E.

**OCTOBER 6-8, 2004**
**TRAINING COURSE ON PRACTICAL GCP COMPLIANCE AUDITING OF TRIALS AND SYSTEMS**
HOTEL COPTHORNE TARA, LONDON, UK

**OCTOBER 14-15, 2004**
**11TH SEMINAR ON MEDICAL APPROACH IN DIAGNOSIS AND MANAGEMENT OF ADRS**
HOTEL SOFITEL PARIS FORUM RIVE GAUCHE, PARIS, FRANCE

**NOVEMBER 8-10, 2004**
**THREE WORLDS ONE VOICE - FIRST JOINT ANNUAL CONFERENCE**
**LINICAL DATA MANAGEMENT**
**NFORMATION TECHNOLOGY**
**ALIDATION**
RAI AMSTERDAM INTERNATIONAL EXHIBITION & CONGRESS CENTER, AMSTERDAM, THE NETHERLANDS

**NOVEMBER 29, 2004**
**TRAINING COURSE ON EUROPEAN REGULATORY AFFAIRS**
HOTEL RENAISSANCE PARIS LA D[illegible]ENSE, PARIS, FRANCE

**NOVEMBER 29-30, 2004**
**FIRST DIA MULTI-TRACK MEETING ON CLINICAL TRIALS AND PHARMACOVIGILANCE**
HOTEL SOFITEL PARIS FORUM RIVE GAUCHE, PARIS, FRANCE

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## Public Health, Patient Needs and Orphan Drugs

Andrea Rappagliosi, Serono International S.A., Switzerland

THURSDAY, MARCH 11, 2004

**08:00 Welcome Coffee and Registration**

**09:00 Session 1**

**PATIENTS, SCIENCE AND INDUSTRY: A EUROPEAN WAY OF PROMOTING RESEARCH AND RAISING AWARENESS TOGETHER**

**Session Co-chairpersons:**

**Ysbrand Poortman, Dutch Alliance Parent Patient Organisations (VSOP), The Netherlands**

**Josep Torrent-Farnell, Fundació Dr. Robert, Spain**

*This session will present a strong and exemplary contribution of the activities of patient organisations towards promoting research and awareness for achieving new medicines for orphan diseases.*

**From Diagnosis to Effective Treatment - A National, European and Global Approach by Family Groups**

*Peter Streng, VSN, The Netherlands*

**Raising Awareness**

*Fern Torquati, Italian Gaucher Association, Italy*

**EPPOSI, Partnering for Better Healthcare Policies towards Treatment and Prevention of Genetic Disease**

*Ysbrand Poortman, Dutch Alliance Parent Patient Organisations (VSOP), The Netherlands*

**10:30 Coffee Break in the Exhibition Area**

**11:00 Session 2**

**FROM CONCEPT TO THERAPY: THE INFLUENCE OF PATIENT GROUPS IN THE RESEARCH AGENDA**

**Session Chairperson:**

**Alastair Kent, Genetic Interest Group, UK**

*The aim of this session will be to demonstrate how working in partnership with patients can make a qualitative change for the better when setting the research agenda. This applies when looking across the spectrum from basic biological research through to the final stages of product development and delivery.*

**The Case of the "European Neuromuscular Centre"**

*Ysbrand Poortman, Dutch Alliance Parent Patient Organisations (VSOP), The Netherlands*

**Gene Therapy and Cystic Fibrosis**

*Rosie Barnes, Cystic Fibrosis Trust, UK*

**Patient Groups and the Pharmaceutical Industry, a New Partnership, the Example of France**

*Jerôme Soletti, Les Entreprises du Médicament (LEEM), France*

**12:30 Lunch in the Exhibition Area**

**14:00 Session 3**

**THE CHALLENGE OF GOLD STANDARDS: CLINICAL TRIALS FOR RARE DISEASES, A PUBLIC HEALTH PERSPECTIVE**

**Session Chairperson:**

**Josep Torrent-Farnell, Fundació Dr. Robert, Spain**

*Rare diseases are defined in terms of prevalence lower than 5/10.000 in habitants in the EU being children, a major subpopulation group. Moreover, other factors such as severity of these conditions, lack of appropriate pharmacological treatment, geographical dispersion, scarcity of experts, fewer reference centres for an early diagnosis and medical management, increasing demand of patients' expectations, ethical concerns in vulnerable population groups, and the impact of emerging therapies, may undermine the conduct of clinical investigations for gathering pre- and postmarketing clinical data of new medicines. This session aims to:*

- *Outline why a new clinical research paradigm for low-prevalence conditions is needed as opposed to well-known methodologies for nonorphan drugs.*
- *Balance scientific evidence, keeping abreast of patients' needs and regulatory requirements with continuing biomedical advances. A case study on anti-cancer orphan designated drugs will be used to illustrate such needs.*
- *Consider some practical approaches to optimise the planning and conduct of clinical trials in these conditions. Special attention will be given to the increasing role of biotech-derived medicinal products.*

**Introduction**

*Josep Torrent-Farnell, Fundació Dr. Robert, Spain*

**Framing the New Paradigm for Clinical Research of Rare Diseases**

*Brendan Buckley, University of Cork, Ireland*

**Low Prevalence Oncology Conditions: Scientific Evidence for Orphan Medicines**

*Rembert Elbers, Federal Institute for Drugs and Medical Devices, Germany*

**Promoting Orphan Drug Research: Transparency, Communication and Public Health**

*Catarina Edfjäll, Actelion, Switzerland*

**Panel Discussion with Eric Abadie, AFSSAPS, France and Andrew Galazka, Serono International S.A., Switzerland**

**15:30 Coffee Break in the Exhibition Area**

**16:00 Session 4**

**POLICY CONTINUITY IN ORPHAN DRUGS: FROM CONCEPT TO PATIENTS**

**Session Chairperson:**

**Ségolène Aymé, Orphanet INSERM SC11, France**

*The European Directive on Orphan Drugs has already had measurable effects on the development of innovative therapies for patients with rare diseases. If the designation process at EMEA is judged satisfactory by all stakeholders, it is time to carefully monitor the trajectory of the designated products, from marketing authorisation to availability and reimbursement in European countries, and to find ways to reduce inequities.*

**Policy Continuity: From COMP Opinion to CPMP Decisions**

*Eric Abadie, AFSSAPS, France*

**Policy Continuity: The Industry Perspective**

*Andrea Rappagliosi, Serono International S.A., Switzerland*

**Policy Continuity: The Patients' Perspective**

*Yann Le Cam, Eurordis, France*

**17:30-18:30 Reception in the Exhibition Area**

## Public Health, Patient Needs and Orphan Drugs

Andrea Rappagliosi, Serono International S.A., Switzerland

FRIDAY, MARCH 12, 2004

**09:00 Session 5**

**SHOULD PATIENTS HAVE A VOICE IN THE EUROPEAN HEALTH AGENDA?**

**Session Chairperson:**

**Rodney Elgie, GAMIAN Europe, UK**

*Health is of the greatest importance to all citizens of Europe. As such, it would seem rational that patients should be entitled to influence politicians who are the ultimate decision makers. The patient's voice within this arena could validly assist in political decisions pertaining to such issues as equity of access, the safety of medicines, information and education, patient mobility and the optimum matching of needs to resources within the European Union. The health debate is essential, but how can such a debate have validity or authenticity without the patient's voice?*

**European Perspective**

*Andre Broeckmans, NV Organon, The Netherlands*

**Region View of Member State**

*José Antonio Valverde, AETSA (Andalusian Agency for Health Technology Assessment), Spain*

**Patient Group Perspective**

*Christoph Thalheim, European MS Platform, Belgium*

**10:30 Coffee Break in the Exhibition Area**

**11:00 Session 6**

**ACCESS TO MEDICINES IN DEVELOPING COUNTRIES**

**Session Chairperson:**

**Yves Juillet, Les Entreprises du Médicament (LEEM), France**

*The TRIPS WTO agreement, finalized in August, will allow practical implementation of compulsory licences in developing countries. It will not solve the problem of access. In this session the WTO agreement will be presented as well as initiatives taken at the international level to enhance research in neglected diseases and international organisation programmes to guarantee quality of drugs provided, specifically antiretrovirals.*

**The WTO Agreement Description and Consequences**

*Eric Noehrenberg, IFPMA, Switzerland*

**Drug Neglected Disease Initiative**

*Yves Champey, DNDI, Switzerland*

**Antiretroviral Certification - WHO Actions**

*Lembit Rägo, WHO, Switzerland*

**12:30 Lunch in the Exhibition Area**

**14:00 Session 7**

**IGNORED OR INFORMED: WHAT SHOULD PATIENTS KNOW?**

**Session Co-chairpersons:**

**Silvia Matile-Steiner, F. Hoffmann-La Roche Ltd., Switzerland**

**Noël Wathion, EMEA, UK**

*The European Parliament (EP) and the Council did not agree in fall 2003 with initial proposals within the review of the pharmaceutical legislation concerning information to patients. It was initially proposed to introduce a pilot project in three disease areas (diabetes, AIDS, asthma and chronic pulmonary disorders). The EP mandated the Commission to consult all interested parties, and to present a report to the EP and the Council putting forward recommendations. The G10 high level expert group had recommended to work out the distinction between advertising and information with all stakeholders, to develop standards to ensure the quality of such information and to assess the extent to which such information meets the needs of patients. On the other hand, in April 2003, EMEA established an EMEA/CPMP Working Group with patients' organisations in order to look at further improvements in the fields of transparency and dissemination of information, product information, pharmacovigilance and EMEA/CPMP interactions with patients' organisations.*

*This session will provide the outcome of the discussions at the level of the EMEA/CPMP Working Group and will allow for a first reaction by patients' organisations and the pharmaceutical industry.*

**Outcome of the Discussions at the Level of the EMEA/CPMP Working Group with Patients Organisations**

*Frits Lekkerkerker, Medicines Evaluation Board, The Netherlands*

**Viewpoint of Patients Organisations**

*Christel Nourissier, Eurordis, France*

**Viewpoint of Pharmaceutical Industry**

*Scott Ratzan, Johnson & Johnson, Belgium*

**Discussion**

**15:30 Coffee Break in the Exhibition Area**

**16:00 Session 8**

**SERVING THE PUBLIC'S HEALTH: HEALTH LITERACY AND MEDGUIDES**

**Session Chairperson:**

**Eleanor Vogt, Institute for the Advancement of Community Pharmacy, USA**

*Two major and pioneer initiatives will be presented:*

*1) The partnership for Clear Health Communication including the "ASK ME 3" campaign and the results of the University of South Florida and Pfizer sponsored Health Literacy Study on Diabetes and Hypertension will be presented along with the interactive tools for patients' disease self-management.*

*2) The Medicines Information Project, a collaborative approach in the UK to meeting patient needs for information will be presented. How patients, health providers, regulators and industry in both the UK and the US are coming together to set goals and outcomes for improving patient education will be analyzed. In this interactive session we will share what we have learned and encourage session participants to share and develop action plans of their own.*

**The Wisdom of the People - A Medication Safe Use Initiative**

*Eleanor Vogt, Institute for the Advancement of Community Pharmacy, USA*

**The Medicines Information Project - A Collaborative Approach to Meeting Patients' Information Needs**

*Steve Mott, Datapharm Communications Ltd., UK*

**Health Literacy - Partnership for Clear Health Communication**

*Barbara DeBuono, Pfizer Inc., USA*

**17:30 Close of the 16th Annual EuroMeeting Prague 2004**



## THURSDAY, MARCH 11, 2004

**08:00 Welcome Coffee and Registration**

**09:00 Session 1**

FUTURE LEGISLATIVE FRAMEWORK FOR NONPRESCRIPTION MEDICINES

**Session Chairperson:**
**Hubertus Cranz, AESGP, Belgium**
*The new EU pharmaceutical legislation will have important implications for nonprescription medicines. Issues to be covered include incentives for moving medicines from prescription to nonprescription status and measures to guarantee the safe use of new indications in self-medication.*

**The European Self-medication Market**
*Chris Weighell, IMS Health, UK*

**New Indications for Self-medication**
*Cheryl Hall, Johnson & Johnson MSD, UK*

**Data Exclusivity for Switch Application**
*Christa Wirthumer-Hoche, Federal Ministry of Health and Women, Austria*

**Safety of Nonprescription Medicines**
*Bernd Eberwein, German Medicines Manufacturers Association (BAH), Germany*

**10:30 Coffee Break in the Exhibition Area**

**11:00 Session 2**

FUTURE LEGISLATIVE FRAMEWORK FOR HERBAL MEDICINAL PRODUCTS

**Session Chairperson:**
**Hubertus Cranz, AESGP, Belgium**
*The session will analyse the major implications of the envisaged directive for traditional herbal medicines for the authorisation in current EU Member States and the enlargement countries.*

**Introduction**
*Hubertus Cranz, AESGP, Belgium*

**The New Directive on Traditional Herbal Medicines**
*Konstantin Keller, BfArM, Germany*

**Impact on National Legislation**
*Tamas Paal, National Institute of Pharmacy, Hungary*

**12:30 Lunch in the Exhibition Area**

**14:00 Session 3**

SCIENTIFIC ASSESSMENT OF MEDICINAL PLANTS

**Session Chairperson:**
**Konstantin Keller, BfArM, Germany**
*The scientific assessment of herbal medicines has been going through an important harmonisation process. The session will look at the achievements so far and future priorities. Incentives for research with herbal medicines will also be discussed.*

**Update on the Work of the EMEA Working Party on Herbal Medicinal Products**
*Konstantin Keller, BfArM, Germany*

**Standardization of Herbal Medicinal Products**
*Urszula Krawczyk, National Institute of Public Health, Poland*

**Incentive for Research with Herbal Medicines**
*Ralf Zerban, Boehringer Ingelheim GmbH, Germany*

**15:30 Coffee Break in the Exhibition Area**

**16:00 Session 4**

FOOD SUPPLEMENTS AND BORDERLINE BETWEEN MEDICINES AND FOOD

**Session Chairperson:**
**Bernd Eberwein, German Medicines Manufacturers Association (BAH), Germany**
*This session will analyse the implementation of the EU food supplements directive on the national level and will discuss further legislative measures, e.g. in the area of quality assurance.*

**Implementation of the Food Supplements Directive in National Legislation**
*Ariane Titz, AESGP, Belgium*

**Further Legislative Measures / Borderline between Medicines and Food**
*Basil Mathioudakis, European Commission, Belgium*

**Quality Assurance of Food Supplements**
*Stephan van Geenen, Roche Consumer Health, Switzerland*

**17:30-18:30 Reception in the Exhibition Area**



**09:00 Session 5**

GENERICS AND THE FUTURE MEDICINES LEGISLATION

**Session Chairperson:**
**Nadene McClay, European Generic Medicines Association, Belgium**
*What will be the result of the review of EU pharmaceutical legislation and how will this affect the generic medicines industry?*

**The Review in the Generics' Context**
*Nadene McClay, European Generic Medicines Association, Belgium*

**Commission Perspective**
*Irene Sacristan-Sanchez, European Commission, Belgium*

**Industry Perspective**
*Frank de Vries, Pharmachemie BV, The Netherlands*

**10:30 Coffee Break in the Exhibition Area**

**11:00 Session 6**

IMPLEMENTATION OF HARMONISED SMPCs: POLICIES AND STRATEGIES

**Session Chairperson:**
**Suzette Kox, Kox Pharma sprl, Belgium**
*The session will address the Heads of Agencies' initiative of Article 30 referrals and the implementation of the outcome at the national level by generic companies. It will explore the feasibility and the limits of the MRP Recommendation of January 2003 and possible ways forward.*

**Implementation of Article 30 Decisions for Generic Products and Feasibility and Limits of the MRFG Recommendation**
*Suzette Kox, Kox Pharma sprl, Belgium*

**EU Perspective**
*Tomas Salmonson, Medical Products Agency, Sweden*

**Viewpoint of a Member State Authority and Issues of Implementation of Harmonised SPCs**
*Harald Schweim, BfArM, Germany*

**A Company's Approach Towards Implementation**
Caroline Kleinjean, Sandoz (Novartis Generics), The Netherlands

**12:30 Lunch in the Exhibition Area**

**14:00 Session 7**

GENERICS AND EU ENLARGEMENT

**Session Chairperson:**
**Beata Stepniewska, European Generic Medicines Association, Belgium**
*The objective of this session is to present specific issues linked to registration of generic products before and after accession from the perspective of the regulatory authority in acceding country, current EU Member State and generic industry. Practical aspects of registration procedures across enlarged Europe - threats and opportunities for generics as well as possible solutions - will be expressed by all interested parties.*

**Generic Industry Perspective**
*Beata Stepniewska, European Generic Medicines Association, Belgium*

**AC Member State Perspective**
*Vesna Koblar, Agency for Medicinal Products, Slovenia*

**Current EU Member State Perspective**
*John Lisman; Medicines Evaluation Board, The Netherlands*

**15:30 Coffee Break in the Exhibition Area**

**16:00 Session 8**

GENERICS: IMPACT ON PUBLIC HEALTH SYSTEMS AND INNOVATION

**Session Chairperson:**
**Greg Perry, European Generic Medicines Association, Belgium**
*The session will explore the impact of generics on public health systems and innovation, and address the conclusions and the implementation of the G10 process.*

**G10 and Generics: Impact on Public Health and Innovation**
*Greg Perry, European Generic Medicines Association, Belgium*

**The Member States' Perspective**
*Rui Santos Ivo, Infarmed, Portugal*

**The Innovation Gap - Will the Generic Pipeline Dry Up?**
*Lukas Pfister, Merck Sharp & Dohme GmbH, Austria*

**17:30 Close of the 16th Annual EuroMeeting Prague 2004**

## Special Populations - Half Track - 4 Sessions

Ingrid Klingmann, Pharmaplex, Belgium
Klaus Rose, Novartis Pharma AG, Switzerland

## THURSDAY, MARCH 11, 2004

**08:00 Welcome Coffee and Registration**

**09:00 Session 1**

**DRUG DEVELOPMENT IN PREGNANCY**

**Session Co-chairpersons:**
**Jean-Marc Husson, Eudipharm, France**
**Jacques Mascaro, Johnson & Johnson Pharmaceutical R&D, UK**

*The session will address scientific and regulatory issues relating to the development of medicinal products within the scope of pregnancy and the related constraints.*

**Regulatory Perspective USA**
*Kathleen Uhl, FDA, USA*

**Regulatory Perspective EU**
*Jan Willem van der Laan, Medicines Evaluation Board, The Netherlands*

**Industry Perspective**
*Patricia Maillère, IRIS, France*

**10:30 Coffee Break in the Exhibition Area**

**11:00 Session 2**

**BETTER MEDICINES FOR CHILDREN: NOT AN EASY ROAD**

**Session Co-chairpersons:**
**Klaus Rose, Novartis Pharma AG, Switzerland**
**Agnès Saint-Raymond, EMEA, UK**

*This session will give an update on the European approach to promotion of paediatric research from the point of view of European health authorities, the pharmaceutical industry, physicians and patients.*

**European Initiative 2004**
*Agnès Saint-Raymond, EMEA, UK*

**Initiative or Incitement**
*Daniel Brasseur, Ministry of Public Health, Belgium*

**Should Europe Provide Incentives to Pharmaceutical Companies?**
*Klaus Rose, Novartis Pharma AG, Switzerland*

**Panel Discussion with Yann Le Cam, Eurordis, France**

**12:30 Lunch in the Exhibition Area**

**14:00 Session 3**

**DRUG DEVELOPMENT IN THE AGING POPULATION**

**Session Co-chairpersons:**
**Sture Eriksson, University of Umea, Sweden**
**Jean-François Thiercelin, Sanofi-Synthelabo, France**

*The development of drugs for the rapidly growing aging population requires an understanding of the physiological, pharmacological and pharmacokinetic changes in this population as well as an appraisal of the clinical and social situation of these patients including the impact of a potential progressive cognitive decline. This session will provide a better understanding of this complex situation and will propose clinical, statistical and trial design approaches to finding more adequate drugs, doses and dosage regimens for this patient population.*

**Drug Development Issues in the Elderly Population**
*Jean-François Thiercelin, Sanofi-Synthelabo, France*

**The Role of Clinical Profiles in the Elderly in Clinical Trials**
*Sture Eriksson, University of Umea, Sweden*

**Innovative Statistical Approaches to the Inhomogeneity of the Elderly Population**
*Joachim Vollmar, PRA International, Germany*

**Open Forum Discussion**

**15:30 Coffee Break in the Exhibition Area**

**16:00 Session 4**

**ETHICAL ISSUES IN STUDIES WITH VULNERABLE POPULATIONS**

**Session Co-chairpersons:**
**Marcel Kenter, CCMO, The Netherlands**
**Ingrid Klingmann, Pharmaplex, Belgium**

*The need for customized medication for special patient populations creates substantial challenges for the protection of vulnerable patients in clinical trials. This session will provide a better understanding of the particular issues of including unconscious patients, very old patients and children in clinical trials, propose solutions and give an opportunity for exchange of experiences.*

**The Informed Consent Process in Unconscious Patients**
*Marcel Kenter, CCMO, The Netherlands*

**Inclusion of Very Old Patients in Clinical Trials**
*Jean-Marie Vetel, Syndicat National de Gerontologie Clinique, France*

**Informed Consent in Paediatric Studies**
*Ingrid Klingmann, Pharmaplex, Belgium*

**17:30-18:30 Reception in the Exhibition Area**

## Dress Code

The dress code for the Annual EuroMeeting is business casual. Slacks and casual dress are encouraged for wear throughout the meeting. Neckties, business suits, or other business attire are acceptable, but not necessary.

***Comfortable shoes are a must!***

## Social Events

***Wednesday, March 10, 2004***

After Wednesday's Plenary and Ask the Regulators sessions, the Distinguished Career and Outstanding Service Awards Ceremony will be followed by the Black and White Theatre Performance and an extensive, international buffet reception at the Prague Congress Centre.

This will not be a formal sit-down dinner, but it has been arranged to increase the opportunity to network and meet colleagues. Admission to the awards ceremony and buffet reception is free of charge to all registered attendees. To help with the arrangements, please indicate your participation on the registration form on the back of this programme. Tickets for guests and partners may be purchased at the registration desk at the Prague Congress Centre.

***Thursday, March 11, 2004***

A New Member Welcome and SIAC Breakfast will be held at the Prague Congress Centre on Thursday morning from 08:00 - 08:45 for new members and/or interested SIAC members.

After the close of Thursday's sessions, a reception will be held in the exhibition area from 17:30 to 18:30. All registered participants are welcome to attend the reception to meet old colleagues and forge new friendships.

## Poster Session/Student Poster Session

Posters selected by the review committee, addressing topics similar to those in the programme, will be on display in the exhibition area. Presenters will make themselves available to discuss their work, Thursday and Friday, during the coffee and lunch breaks, at the congress centre.

The Poster Review Committee will select the three best student posters, and the winning authors will receive a EuroMeeting Student Poster Prize. The prizes will be awarded at the Student Poster Award Ceremony on Thursday, March 11, 2004, at 17:30 in the Exhibition Area of the congress centre.

## Exhibit Hall Opportunities

**Scientific Exhibit**

There will be 96 companies exhibiting in the Prague Congress Centre, which also serves as the site of coffee breaks, luncheons and receptions.

**Employment Opportunities**

DIA will provide employment opportunities electronically via the job bank located in the DIA booth. Participants will also have the ability to post positions on this system at the EuroMeeting.

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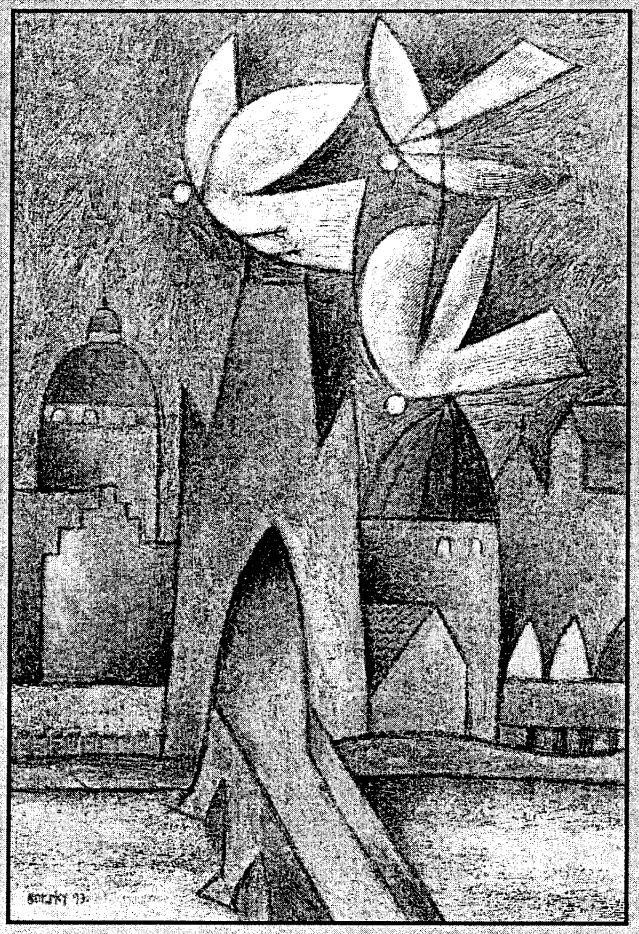
# EUROMEETING

## PRAGUE 2004



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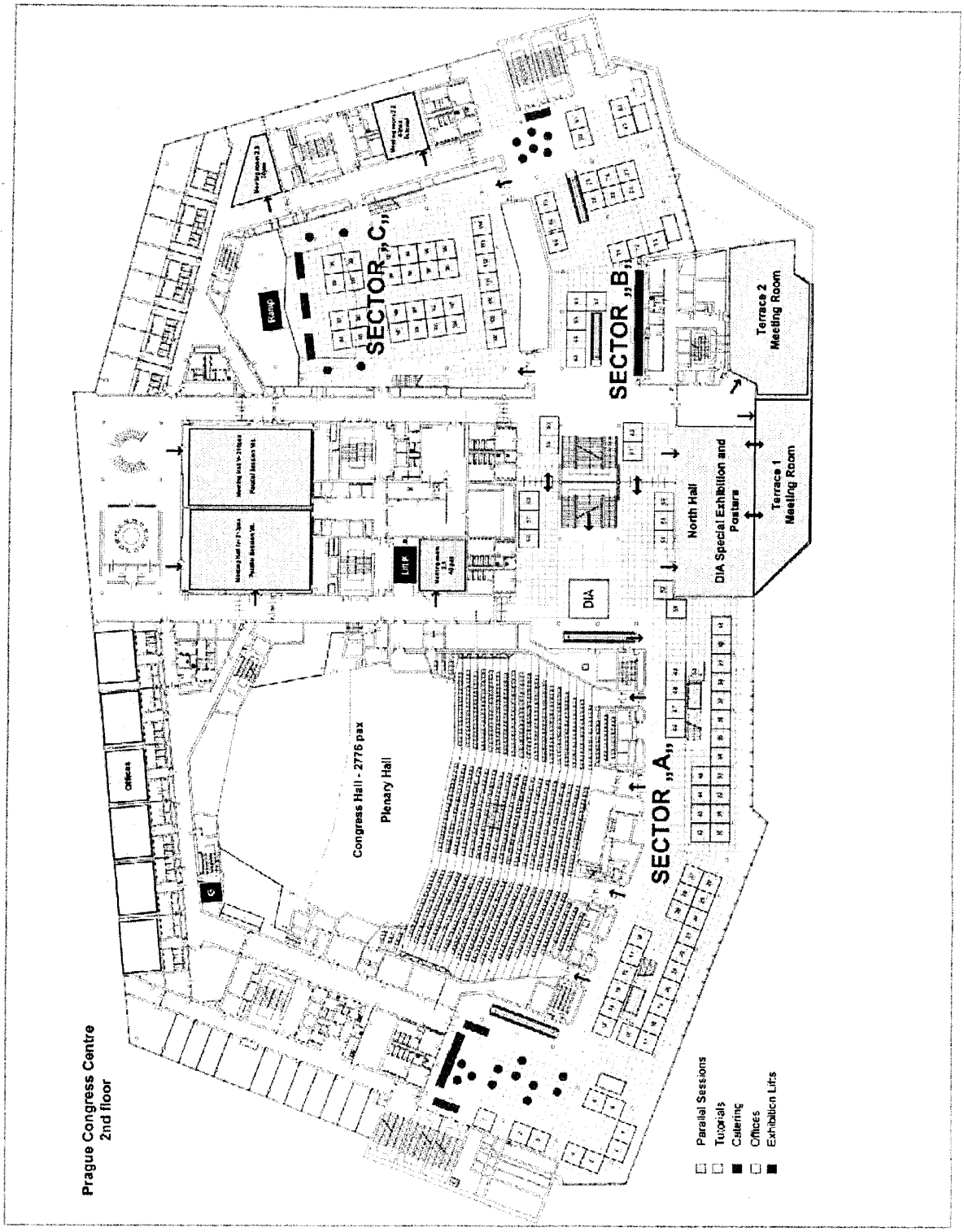

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# SUMMARIES OF EXHIBITORS' SERVICES

**ABX-CRO advanced pharmaceutical services** **Booth 112**
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Biomedical Systems provides centralized diagnostic services including 12-lead ECG, Spirometry, Holter , Ambulatory Blood Pressure, Echocardiography, Pulse Oximetry, Cardiac Event and Obstetrical Monitoring.

**Capio Diagnostik** **Booth 63**
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**Web Address: www.capiodiagnostik.dk**
Capio Diagnostik is Scandinavia's largest provider of laboratory services. Capio Diagnostik Clinical Trials is a GCP compliant and GLP certified/ISO 17025 accredited central lab service. Alliance partners in US, Australia, South Africa, and Israel.

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CCRA is a UK trade association of organisations involved in clinical development support services to the pharmaceutical industry. International members, especially within Europe, may benefit from networking with their UK counterparts.

**Clinical Data Care** **Booth 86**
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DOCS International is a leading European staffing company dedicated to the healthcare industries. Established in 1997, DOCS has successfully entered the international market and integrated in the local markets of Germany, France, UK and the Nordics.

**Elsevier** **Booth 17**
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Elsevier has successfully developed a variety of bibliographic databases in many scientific areas, including Biomedicine and Pharmaceutical Sciences. EMBASE.com combines Embase and Medline databases online. Please visit booth 17 for more information.

**EMEA** **Booth 53**
**Telephone: +44 20 74 18 84 26** **Fax: + 44 20 74 18 86 70**
**Email: beatrice.fayl@emea.eu.int**
**Web Address: www.emea.eu.int**
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Entimo AG was founded in autumn 2002 as a spin-off of a German IT company's long-established pharmaceutical IT solutions business. Its primary focus is providing eR&D solutions and professional services to the pharmaceutical and crop science sectors.

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17TH ANNUAL

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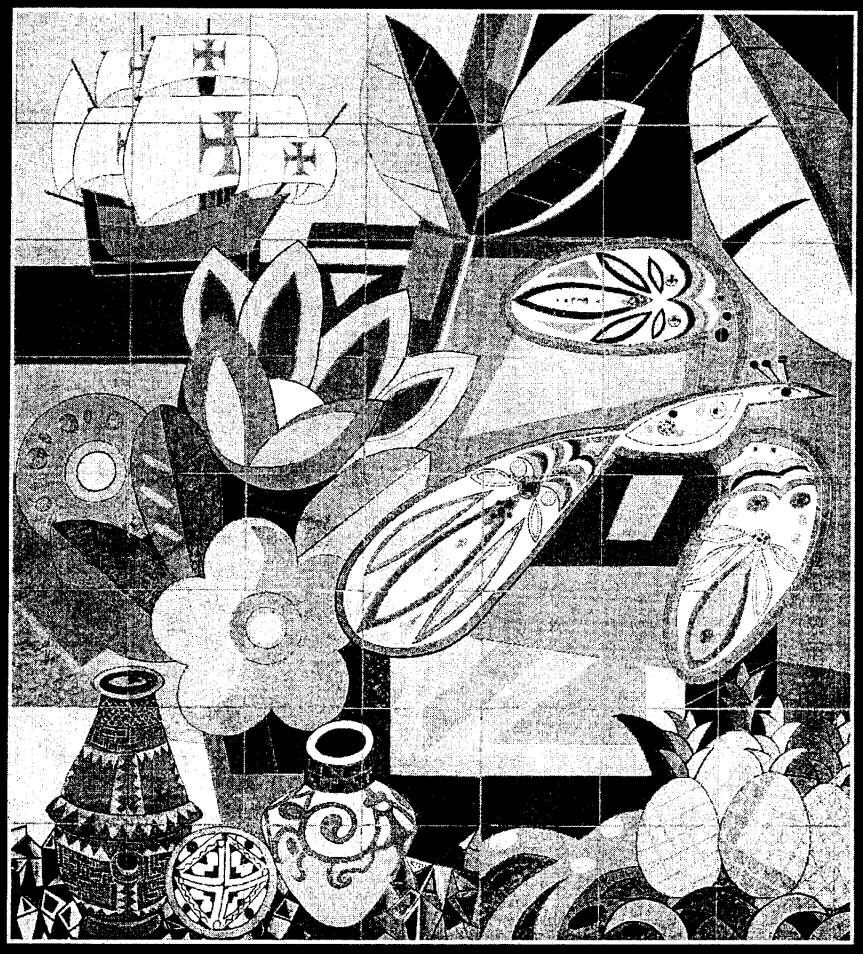

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# EUROMEETING PRAGUE 2004

# Poster Session Abstracts

## *Student Poster Session Abstracts*

# List of Poster Authors



# List of Student Poster Authors

# List of Poster Abstracts

## P1
## Development of a Multi-Language Web-Based Pharmacovigilance Training Program

H. Ward, C. Anderson, and J. Casoy
(Wyeth Pharmaceuticals USA)

**Objectives:**
To develop an easily accessible, functional and effective program on adverse event reporting training for global pharmaceutical company personnel. Requirements for the program included understandable content in local language, provision of necessary reporting tools (forms and contact information), and metrics to demonstrate completion and understanding of the material.

**Methods:**
Training all employees of a global pharmaceutical company on adverse event reporting is a challenge. New employees are frequently hired, and existing employees should receive periodic re-training. Training must be provided in a way that is available immediately to new employees, understandable to all employees, and measurable by management with a test.
Methods: A Macromedia Flash-based program was developed and approved in English. The template text was provided for translation into two pilot languages (one Roman alphabet-based, Portuguese; one non-Roman alphabet-based, Hindi) and customized with specific local information (telephone, fax number, e-mail address, etc.). The program included a mandatory assessment (test) with immediate feedback on correct or incorrect answers. Designated system administrators track completion rates. Technical and translation issues encountered during the pilot program are described.

**Results:**
Based on the information gained during pilot testing, the program is in development for use in 35 countries in Europe, Latin America, Asia, and North America. Demonstrated advantages of the program are the ability to provide adverse event reporting training in local language, via the Internet, to new employees promptly upon their employment, in a measurable manner (with a test) for a cost that is less than traditional classroom based training.

**Conclusions:**
A train company employees in their local language on adverse event reporting, and provided management a method for tracking completion of the training.

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## P2
## Extending Drug Information across Europe

Marité Ode, Claire Foster, Thomas Merrifield, Lynn Weddell and Ivor Cowlrick
(Fujisawa GmbH, Germany)

**Objectives:**
Fujisawa Pharmaceuticals is a global company with 'centres' in Japan, the US and Germany. Lead products include immunosuppressive and dermatological preparations, which are available in approximately 70 countries worldwide. The European web site was launched in early 1999 and has been extended across Europe. With both consumers and the medical community in mind, a balance was sought to provide information on products and target diseases to an expanding European community.

**Methods:**
Following the creation of a standard template and design, additional functions were added. The implementation of a content management system permitted changes to the web site independent of any external party which saves time and costs. This ongoing process includes reviewing content and implementing improvements. As the products are prescription only medicines, web site structure, style and content are important. Vivid colours, complicated graphics and gimmicks are avoided. Quality medical information targeted for health professionals is provided by on-line registration or by DocCheck (DocCheck Medical Services, Köln), and access to password-protected sections.

**Results:**
The web site offers:
- Company and European subsidiary contact details (links to other centres)
- 'Parent' site in English language
- News, announcements, company awards, press releases
- Information and prescribing information and slide databases
- A calendar of important events (>200 congresses and meetings)
- Medical and media enquiries, general information by e-mail
- Information on disease areas (patient video, CD-ROM in 8 languages)
- Links to support groups, congress organisers and other related organisations

Immunological and dermatological sections can be reached from the home page. Each of the company's European subsidiaries has also opted for a local web site created similarly to the parent site and conforming to local regulations. Germany, Austria, Spain, Italy and Sweden are all currently represented in their local languages. Web sites for the remaining EU member states are also in preparation with plans to accommodate new EU entrants.

**Conclusions**
A rapid increase in visits to the web site from 10,000 hits/month in 2000 to 150,000 hits/month in 2003 is matched by a parallel increase in registered health care professionals from Europe and beyond

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## P3
## Knowledge and Acceptance of Clinical trials Among Breast Cancer Patients

B. Häussler, and M. Kurepkat
(Clinische Studien Gesellschaft GmbH, Germany)

**Summary:**
Women with breast cancer only know a few details about clinical trials. However, the acceptance is high. And it even increases after participation in a clinical trial. Comprehensive educational work about clinical research could facilitate recruitment fundamental.

**Background:**
In Germany it is hard to recruit the required number of suitable patients for a clinical trial. One of the reasons might be that only few people are open towards such studies due to a lack of knowledge. At the moment there are hardly any valid insights about how potential participants perceive such studies as well as how patients who went through it experienced those.

**Methods:**
Subjects were asked to fill out a standardized questionnaire. The questionnaires were distributed among women in two university hospitals, self-help groups and medical practices of office-based gynaecologists. 142 actual breast cancer patients as well as women who had breast cancer in the past were being interviewed. 65 of those women had already taken part in a clinical trial. Besides sociodemographice data all respondents were being probed for their degree of knowledge in terms of clinical trials.

**Results:**
Particular features of clinical trials are unknown. 68,8% has no knowledge about the procedure of randomisation, 56,3% is unsure of the relevance of SAE. Additionally, the perception of clinical trials was explored: 89% of respondents stated that they would participate in a study if it were necessary. There is a huge difference between women who have taken part in a study and women without this experience. A 91% of former trial participants would definitely recommend taking part in such a trial to other women. The vast majority of female interviewees associated a higher quality of care that comes along with those types of trials (87,5% better control of the disease, 64,9% best practice).

**Conclusion:**
Potential trial participants are open towards taking part in them. There is a difference between former participants and non-participants. 80% of non-participants with little knowledge about it are uncertain/declining about it. The need to inform both groups is extremely high. Giving more information about clinical studies in general could probably improve the number of recruited participants.

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# List of Poster Abstracts

## P4
## Literature Reviews of Off-label Drug Use in Pregnancy: A Case Study

Gail Head, PhD.,
(PAREXEL International, UK)

**Objectives:**
To review the literature for efficacy and safety of a drug with substantial off-label use in pregnancy.

**Methods:**
Two CRO medical writers reviewed publications identified from 23 databases, and data extracted into a customised excel database. A medical officer from the sponsoring pharmaceutical company reviewed database output against each publication. Adverse events were coded using standard dictionaries. Data were reviewed and summarised from three perspectives:

1. Randomised, blind, controlled studies versus a drug licensed for the same indication in pregnancy
2. All adequate controlled studies.
3. All studies. Within the Medical Writing Department an expert report, tabulations and listings were produced.

**Results:**
Of 55 publications, 47 were summarised. Safety information included maternal, foetal or neonatal deaths, SAEs and other AEs, neonates admitted to the neonatal ICU and neonates with Apgar scores <7 at 5 minutes. Efficacy information included four categorical outcomes, and continuous measures of absolute status, improvement from baseline, and neonatal birth weight. In controlled trials versus the licensed comparator, consistent differences in favour of the off-label drug were seen for both safety and efficacy. The expert report and data tabulations enabled a judicious assessment of the efficacy and safety of the drug without the need for a specific clinical trial program in this specialised patient population, thus avoiding many of the associated ethical and emotive issues.

**Conclusion:**
Systematic literature reviews can assess the risk benefit of off-label use in pregnancy and support subsequent line extension dossiers.

## P5
## Selection Criteria when Evaluating Laboratories

Hermann Schulz, MD, and Wolfgang Pohl
(INTERLAB central lab worldwide, Germany)

**Objectives:**
To show selection criteria, which have to be held in mind when evaluating, centralized laboratories: which questions are essential when selecting a central laboratory and why many of them are never asked.

**Methods:**
Use of centralized laboratories is becoming very common in Europe but nevertheless sponsors or CROs do not always professionally perform selection of a laboratory to support a multicenter and multinational study. An analysis is shown how sponsors approach a central laboratory which questions they raise and which they forget.

**Results and Conclusions:**
This poster provides a comprehensive listing of questions, which must be raised in the selection process when outsourcing laboratory services is seeked.

## P6
## The Use of Interactive Voice Response (IVR) Systems in Measuring Clinical Endpoint Data in Crohn's Disease Studies

Dr Bill Byrom, Ann-Marie Shepherd, (ClinPhone Group Ltd. UK), and
Dr Yamin Khan, (Pharm-Olam International UK)

**Objectives:**
The primary efficacy measurement in Crohn's disease studies is the Crohn's Disease Activity Index (CDAI). This index is a utility score, calculated from patient diary data (number of stools, general well-being, temperature etc.), clinical assessment data (disease symptoms, abnormal masses) and laboratory data (haematocrit) by applying an algorithm. The diary data are typically collected on paper, and the CDAI calculation performed by investigators with the aid of a worksheet. Manual calculation is subject to human error, and furthermore can be burdensome. Collection of primary efficacy data using paper diaries can produce data that is lacking in quality and integrity.
Electronic diary applications overcome these issues, the most commonly used solutions being IVR and handheld devices. We demonstrate how IVR provides an effective means of diary data collection and CDAI calculation in Crohn's disease studies.

**Methods:**
High patient compliance and acceptability are associated with the use of IVR-diary applications Real-time fax/email notifications to site enable proactive encouragement of patients to continue entering diary data on a daily basis. Because both patient and investigator can access the central IVR application, investigators can use telephone/web-interfaces to combine laboratory and clinical data with the patient diary records. This integration enables automatic CDAI calculation, which can be reported to the study site or held confidentially Consequently, high quality, robust CDAI scores can be delivered across the project team on a real-time basis.

**Conclusion:**
IVR systems are well suited to collection of daily symptoms diary data in Crohn's disease. The ability for the investigator to access and review these data in real-time, and enter the required clinical parameters into the common database offers significant advantages over the other methods commonly employed to calculate CDAI scores.

# List of Student Poster Abstracts

## SP1

## EU Directive 2001/20/EC: Impact on the Initiation of Clinical Trials in the Accessing Countries.

I. Bertrand, E. Viant-Gobel, and A. Serve (D E S S. France)

**Objectives:**
The aim of this poster is to show how to initiate clinical trials in the Accessing Countries, before and after the implementation of the Directive 2001/20/EC, with emphasis on the roles of Ethics Committees (ECs) and Competent Authorities (CAs).

**Methods:**
These data were compiled from two key sources:
- An extensive search of the websites of the local medicinal product agencies and/or CAs, ECs, the IDRAC database and the professional organisations;
- Surveys sent to the relevant professionals.

**Results:**
The items covered are:
- Details on the clinical trial submission procedure (sequential or parallel to the CAs and ECs);
- ECs' organisations and applications to the ECs (process, required documents, timelines, fees);
- CAs' names and applications to the CAs (process, required documents, timelines, fees).

The findings of the review are presented in a table, which reflects the situation before and after the implementation of the above-mentioned Directive.

**Conclusion:**
This synopsis attempts to highlight the major aspects in the initiation of the clinical trials and the ways each Accessing Country will interpret the EU Directive 2001/20/EC.

NB: The information provided at the time of presenting this abstract might be incomplete due to the ever-changing situation.

## SP 2

## EU Directive 2001/20/EC: Impact on the Initiation of Clinical Trials in Belgium, Denmark, Finland, Luxembourg, The Netherlands and Sweden.

M. -E. Beydon, A. Girard, and S. Lordey (D.E.S.S. France)

**Objectives:**
The aim of this poster is to show how to initiate clinical trials in Belgium, Denmark, Finland, Luxembourg, The Netherlands, and Sweden, before and after the implementation of the Directive 2001/20/EC, with emphasis on the roles of Ethics Committees (ECs) and Competent Authorities (CAs).

**Methods:**
These data were compiled from two key sources:
- An extensive search of the websites of the local medicinal product agencies and/or CAs, ECs, the IDRAC database and the professional organisations;
- Surveys sent to the relevant professionals.

**Results:**
The items covered are:
- Details on the clinical trial submission procedure (sequential or parallel to the CAs and ECs);
- ECs' organisations and applications to the ECs (process, required documents, timelines, fees);
- CAs' names and applications to the CAs (process, required documents, timelines, fees).

The findings of the review are presented in a table, which reflects the situation before and after the implementation of the above-mentioned Directive.

**Conclusion:**
This synopsis attempts to highlight the major aspects in the initiation of the clinical trials in Belgium, Denmark, Finland, Luxembourg, the Netherlands, and Sweden, and the ways each Member State will interpret the EU Directive 2001/20/EC.

NB The information provided at the time of presenting this abstract might be incomplete due to the ever-changing situation.

## SP3

## EU Directive 2001/20/EC: Impact on the Initiation of Clinical Trials in Austria, Germany, France, Ireland and UK

J. Chriqui, A. Fuller, and A. Mergey (D E.S.S. France)

**Objectives:**
The aim of this poster is to show how to initiate clinical trials in Austria, Germany, France, Ireland and the United Kingdom, before and after the implementation of the Directive 2001/20/EC, with emphasis on the roles of Ethics Committees (ECs) and Competent Authorities (CAs).

**Methods:**
These data were compiled from two key sources:
- An extensive search of the websites of the local medicinal product agencies and/or CAs, ECs, the IDRAC database and the professional organisations;
- Surveys sent to the relevant professionals.

**Results:**
The items covered are.
- Details on the clinical trial submission procedure (sequential or parallel to the CAs and ECs);
- ECs' organisations and applications to the ECs (process, required documents, timelines, fees);
- CAs' names and applications to the CAs (process, required documents, timelines, fees).

The findings of the review are presented in a table, which reflects the situation before and after the implementation of the above-mentioned Directive.

**Conclusion:**
This synopsis attempts to highlight the major aspects in the initiation of the clinical trials in Austria, Germany France, Ireland and the United Kingdom, and the ways each Member State will interpret the EU Directive 2001/20/EC.

NB: The information provided at the time of presenting this abstract might be incomplete due to the ever-changing situation

## SP4

## EU Directive 2001/20/EC: Impact on the Initiation of Clinical Trials in Greece, Italy, Portugal and Spain.

M. Leduc and J. Penitot (D E.S.S. France)

**Objectives:**
The aim of this poster is to show how to initiate clinical trials in Greece, Italy, Portugal and Spain, before and after the implementation of the Directive 2001/20/EC, with emphasis on the roles of Ethics Committees (ECs) and Competent Authorities (CAs).

**Methods:**
These data were compiled from two key sources:
- An extensive search of the websites of the local medicinal product agencies and/or CAs, ECs, the IDRAC database and the professional organisations;
- Surveys sent to the relevant professionals.

**Results:**
The items covered are:
- Details on the clinical trial submission procedure (sequential or parallel to the CAs and ECs);
- ECs' organisations and applications to the ECs (process, required documents, timelines, fees);
- CAs' names and applications to the CAs (process, required documents, timelines, fees).

The findings of the review are presented in a table, which reflects the situation before and after the implementation of the above-mentioned Directive.

**Conclusion:**
This synopsis attempts to highlight the major aspects in the initiation of the clinical trials in Greece, Italy, Portugal and Spain, and the ways each Member State will interpret the EU Directive 2001/20/EC.

NB: The information provided at the time of presenting this abstract might be incomplete due to the ever-changing situation.

# List of Student Poster Abstracts

## SP5
## Prospective Review of the Directive 2001/20/EC Implementation in the Future Enlarged European Union.

B. Calvet, A. Corbé, and C. Vechot, (D.E.S.S. France)

**Objectives:**
The aim of this poster is to show the main implications of the Directive 2001/20/EC on the Clinical Trial approval procedures in the future enlarged European Union.

**Methods:**
These data were compiled from two key sources:
- An extensive search of the websites of the local medicinal product agencies and/or Competent Authorities (CAs), Ethics Committees (ECs), the IDRAC database and the professional organisations;
- Surveys sent to the relevant professionals.

**Results:**
The review of the collected data points out a number of positive aspects and of concerns.
The assessment is presented in three parts, which are:
- The achievements;
- The national specificities;
- The outstanding issues.

**Conclusion:**
The review attempts to draw a summary of the achievements and to point out concerns in the approval of Clinical Trials.

NB: The information provided at the time of presenting this abstract might be incomplete due to the ever-changing situation.

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## SP6
## Schedule of the Directive 2001/20/EC Implementation

D. Hallé, and M. Mac Nair (D.E.S.S. France)

**Objectives:**
The aim of this poster is to give the schedule of the Directive 2001/20/EC implementation and the possible related transition phases in the future enlarged European Union.

**Methods:**
These data were compiled from two key sources:
- An extensive search of the websites of the local medicinal product agencies and/or Competent Authorities (CAs), Ethics Committees (ECs), the IDRAC database and the professionals organisations;
- Surveys sent to the relevant professionals.

**Results:**
The poster is presented as a general summary table. The data provided are related to the dates of implementation and possible transition phases in each of the twenty-five concerned countries.

**Conclusion:**
This review gives an overall picture of the implementation of the Directive 2001/20/EC and transition phases in the fifteen current Member States and the ten accessing countries.

NB: The information provided at the time of presenting this abstract might be incomplete due to the ever-changing situation.

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## SP7
## Regulatory Challenges for Tissue Engineering Product Development

Maarit Heinonen, Outi Nieminen and Katrina Nordström
(Helsinki University of Technology, Finland)

**Objectives:**
The future of cell-based and related therapies in Finland is cautiously optimistic. Regulation for cell-based therapies is under preparation in the EU and the emerging regulation will have a major impact on the future of the new technologies. The aim of the present study is to contribute to an insight for building a future regulatory framework within the EU, which would facilitate bringing safe, ethically acceptable and commercially viable products to the markets without unreasonable delay.

**Methods:**
Developers of TE-products, regulatory authorities, experts on infection risks and patenting officials were interviewed in Finland and abroad. Altogether 22 experts were interviewed.

**Results:**
A centralised evaluation seems the only way to ensuring a uniform assessment of TE products, a feature that is necessary for the access to the common EU-market. Evidently, the existing regulation for cell-based and related therapies is not sufficient for covering all product categories, however, a new regulatory category may not be the solution.

**Conclusion:**
There is a general consensus that some of the products do resemble medicinal products and some medicinal devices. Developers feel that current legislation is not suitable for autologous and allogenic products, but on the other hand, the safety risks of TE products are regarded as high. From a regulatory point of view, this should lead to a legislation that would be at least as stringent as current legislation for medicinal products.

Thus, a new directive would be feasible only if the level of requirements for a TE product is set clearly below the standards of a medicinal product. This, however, is an unlikely scenario, but future regulatory requirements for TE products will probably not be stricter than the current requirements for medicinal products.

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## SP8
## Technical, Commercial and Regulatory Aspects of Bio Products Scale-up

Marko Närhi and Katrina Nordström
(Helsinki University of Technology, Finland)

**Objectives:**
The aim of the present study was to find out what the future needs of the biotechnology industry in Finland will be and what types of technologies are needed for the scale-up and manufacturing of biopharmaceuticals and biomaterials. Furthermore, the aim was to elucidate what regulatory requirements should be anticipated in the designing of future manufacturing capacity, processes and facilities.

**Methods:**
Information from Finnish pharmaceutical and biotechnological associations as well as individual companies was gathered via the Internet and by e-mail questionnaires. Personal interviews were conducted with representatives of thirteen companies, including biopharmaceutical and biomaterial developers, contract manufacturing organizations and other service providers. National regulatory authorities were also interviewed.

**Results:**
Finnish biopharmaceutical companies focus mainly on antibodies, therapeutic proteins, vaccines and viral vectors. Biomaterials companies are producing primarily self-reinforced and restorable polymer implants, fibre reinforced composites, bioactive glass preparations, starch-based biopolymers or biotechnologically manufactured recombinant collagen and gelatine. General biotechnological or polymer processing methods manufactures both biopharmaceuticals and biomaterials, but the manufacturing requires clean rooms and the requirements for the purity of the end product are tight.

**Conclusion:**
Most Finnish biopharmaceutical companies have their own pilot scale clean rooms for manufacturing, but as yet no biopharmaceutical is being produced in commercial scale manufacturing facilities. However, as most biopharmaceutical companies are aiming to licence products before phase III clinical studies, there may not be a need for phase III scale manufacturing facilities yet. On the other hand, some biomaterial companies are already manufacturing their products commercially and rely on their own manufacturing premises. The more stringent regulatory requirements for biopharmaceuticals production are more of a hurdle than are the requirements for biomaterials production. Interpretation of differing EMEA and FDA policies is a challenge for the producer as are also the problems associated with the outsourcing of commercial production.

# 附錄三

## The future Committee on Herbal Medicinal Products

### Impact on current activities of the HMPWP

Dr. Konstantin Keller

Federal Institute for Drugs and Medical Devices, Bonn

Chair of the Herbal Medicinal Products Working Party, European Medicines Evaluation Agency, London

BfArM emea

## Achievements and Challenges

Comprehensive set of guidelines on the assessment of quality, safety and efficacy of herbal medicinal products and monographs (core-data) is available:

www.emea.eu.int

Close co-operation with European Pharmacopoeia and WHO traditional medicines program

## Achievements and Challenges

Guidelines are general recommendations that have no direct legal value; they may be implemented or not by national authorities in the EU

Purely traditional products with insufficient scientific data on efficacy are not adequately addressed by legislation

Enlargement of the EU from 15 to 25 Member States will require streamlining of procedures and clarity in legislation

## EMEA Committee on Herbal Medicinal Products

1st May 2004 New EU Members

| | | |
|---|---|---|
| Austria | Germany | Malta |
| Belgium | Greece | Netherlands |
| Cyprus | Hungary | Poland |
| Czech Republic | Ireland | Portugal |
| Denmark | Italy | Slovak Republic |
| Estonia | Latvia | Slovenia |
| Finland | Lithuania | Spain |
| France | Luxembourg | Sweden |
| | | United Kingdom |

## Key elements of the new EU legislation

### Committee for Herbal Medicinal Products

Article 16 h)

25 *Members* / 25 *Alternates* from all Member States chosen on the basis of their specific scientific competence

max. 5 additional *co-opted Members* if additional specific scientific competence is needed; chosen among experts nominated by Member States or EMEA

Members may be accompanied by *Experts*

## The Future Committee on Herbal Medicinal Products

*The interim period*

Timeframe for implementation
Member States: 18 months (new applications)

EMEA
approx. April 2004 (Title IV of the regulation), max. 18 months (Directive on trad. HMP)

Implementation in the Member States may depend on input from the new Herbal Committee (list, monographs, classification etc.)

## The Future Committee on Herbal Medicinal Products

*The interim period*

HMPWP will organise two additional meetings in preparation of the implementation of the Directive

*However*

Some delegations expressed concerns on the legal value of such work

## The Future Committee on Herbal Medicinal Products

*The interim period*

*Reasons*

The Status of the new Committee will differ substantially from the present status

The composition of the new Committee will differ from that of the HMPWP (new MS, experts)

A new interpretation of the legislation, e.g. on well-established use, may develop

## The Future Committee on Herbal Medicinal Products

*The interim period*

*Reasons*

Decisions of the new Committee are, in principle, independent from past decisions

*However*

The high scientific quality of the documents of the HMPWP is acknowledged by the majority of the Member States, WHO, scientific organisations and regulatory agencies outside the EU

## The Future Committee on Herbal Medicinal Products

*Current activities*

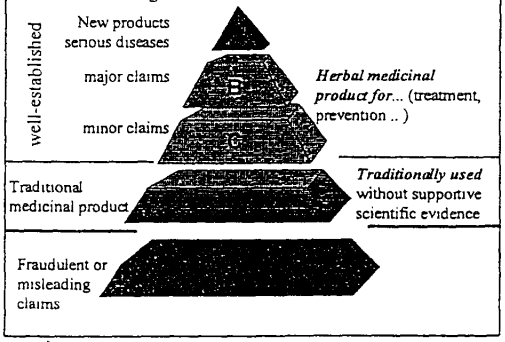
existing documents are an excellent scientific basis for the fast implementation of the new Directive

a first draft proposal for the structure of a possible list of traditional HMP is going to be prepared

safety of herbal substances remains a priority

core-data state the level of evidence (I-IV) found in literature to allow future re-allocation to the traditional or to the well-established area

## Grading of Evidence / Recommendations




## Concept paper on the implementation of different levels of scientific evidence in core-data for herbal drugs

February 2004

**A) High level of evidence (Level Ia, Ib; Grade A)**

The claims - "For the treatment, cure or management of any serious disease or disorder" and - "For the prevention of any serious disease or disorder" should be reserved for products with high level of evidence only

**Concept paper on the implementation of different levels of scientific evidence in core-data for herbal drugs**

**B) Minimum requirement:**
**Medium level of evidence (Level IIa, IIb, III; Grade B)**

The following claims may be acceptable:

- Reduction of the risk of a disease / disorder
- Reduction in frequency of a discrete event
- Aids/assists in the management of a named symptom / disease / disorder
- Relief of symptoms of a named disease or disorder

**Concept paper on the implementation of different levels of scientific evidence in core-data for herbal drugs**

**C) Minimum requirement:**
**General evidence (Level IV, Grade C)**

The following claims may be acceptable:

Relief or management of symptoms or description of a pharmacological action related to management of symptoms of a minor, self-limiting disease / disorder that does not require medical intervention for diagnosis or monitoring.

If general evidence is submitted, additional supporting scientific evidence, e.g. pharmacological data, may be necessary for acceptance.

## The Future Committee on Herbal Medicinal Products

*Current activities*

*Safety*

Final position papers on herbal medicinal products containing

Asarone
Methyleugenole
Estragole
Capsicum/Capsaicin

## The Future Committee on Herbal Medicinal Products

*Current activities*

*Pharmacovigilance*

Draft position statements on herbal medicinal products containing

Chamomile

Soya - preparations / Arachis oil

## The Future Committee on Herbal Medicinal Products

*Current activities*

*Efficacy*

Final core data for

Lini semen
Primulae radix
Salicis cortex
Thymi herba
Menthae piperitae aetheroleum
Menthae piperitae folium

## The Future Committee on Herbal Medicinal Products

*Current activities*

*Efficacy*

Draft core data for

Urticae radix

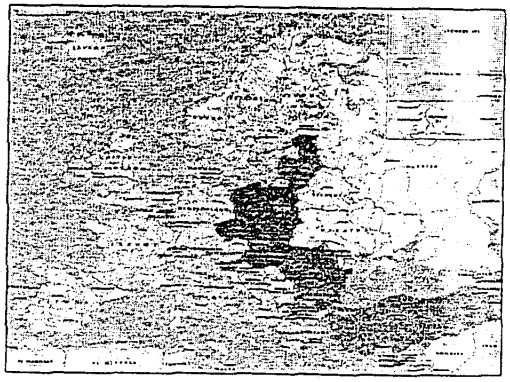
Concept paper on the implementation of different levels of scientific evidence in core data

SOP "Recording of core-data for herbal drugs .."

## Key elements of the new EU legislation

*Article 16c*

1. The application shall be accompanied by:
   (c) bibliographical or expert evidence ... that the medicinal product in question, ... has been in medicinal use throughout a period of at least thirty years preceding the date of the application, including at least 15 years within the Community. At the request of the Member State where the application for traditional-use registration has been submitted, the Committee for Herbal Medicinal Products shall draw up an opinion on the adequacy of the evidence of the long-standing use of the product ...



## Key elements of the new EU legislation

*Article 16c*

4. Where the product has been used in the Community for less than 15 years, but is otherwise eligible for simplified registration, the MS where the application for traditional-use registration has been submitted shall refer the product to the Committee for Herbal Medicinal Products. ... The Committee shall consider whether the other criteria for a simplified registration ... are fully complied with. If the Committee considers it possible, it shall establish a Community herbal monograph ... which shall be taken into account by the Member State when taking its final decision.

## Key elements of the new EU legislation

*Article 16c*

1. The application shall be accompanied by:

   (d) a bibliographic review of safety data together with expert report, and where required by the competent authority, upon additional request, data necessary for assessing the safety of the medicinal product..

## Key elements of the new EU legislation

The Committee for Herbal Medicinal Products will prepare:

**Article 16f**

A list of traditional herbal drugs/-preparations/combinations that can be used for the registration procedure

**Article 16h**

Monographs on herbal drugs/-preparations that may be used for traditional use registrations or full marketing authorisations of well-established herbal medicinal products

## Key elements of the new EU legislation

*Article 16f*

1. A list of herbal substances, preparations and combinations thereof shall be established in accordance with the procedure referred to in Article 121(2). The list shall contain with regard to each herbal substance the indication, the specified strength and the posology, the route of administration and any other information necessary for the safe use of the herbal substance.

## The Future Committee on Herbal Medicinal Products

Herbal medicinal products are part of the European cultural heritage. Concerns have been raised that the new EU legislation may reduce therapeutic options available to consumers and to health professionals.

Scientific excellence alone will not be sufficient for success.

Building confidence in consumers, health professionals and applicants will be the first challenge to the Committee.

Confidence requires respect for different cultures together with a well-balanced assessment and a high degree of transparency

# 附錄四

## Improving the legal framework for herbal medicinal products in the European Union

### The new EU Directive on traditional herbal medicinal products

Dr. Konstantin Keller

Federal Institute for Drugs and Medical Devices, Bonn

Chair of the Herbal Medicinal Products Working Party, European Medicines Evaluation Agency, London

BfArM emea

## Initiatives to adapt EU legislation

**1. Review of the pharmaceutical legislation**

http://pharmacos.eu.int

- proposed Regulation defining the role of the European Medicines Agency
- proposed Directive defining marketing authorization procedures and requirements

## Initiatives to adapt EU legislation

**2. Proposal for a Directive on traditional herbal medicinal products**

first proposal by the EC 17 January 2002

first reading adopted by EP 21 November 2002

Council common position 4 November 2003

2nd reading adopted by EP 17 December 2003

positive opinion from EC 13 February 2004

adoption by EU Council of Ministers expected March 2004

## Key elements of the new EU legislation

**Simplified procedure for access to the market:**

**Article 16a**

***Registration*** **of traditional herbal medicinal products**

applicable to traditional herbal medicinal products; vitamins and minerals may be added if their action is ancillary to the herbal constituent(s)

Preference to full marketing authorisation, if possible

Definition of a "traditional" product:

> 30 years of medicinal use on the territory of the EU or > 15 years in and > 15 years outside the EU

Deviations may be decided by the Herbal Committee

## Key elements of the new EU legislation

**Simplified procedure for access to the market:**

**Article 16c**

**Dossier requirements**

Administrative and Pharmaceutical dossier identical to "full" marketing authorisation

Bibliographical or expert evidence on traditional use of the product or a corresponding product

Expert report on safety

all safety-studies that are necessary may be requested by the Agency

## Key elements of the new EU legislation

**Simplified procedure for access to the market:**

**Inclusion Criteria (Article 16a)**

Indication(s) appropriate to traditional herbal medicinal products

use without the supervision of a medical practitioner for diagnosis, prescription or monitoring of treatment

specified strength / posology

Only oral use, external use and inhalation

## Key elements of the new EU legislation

**Simplified procedure for access to the market:**

**Inclusion Criteria (Article 16a)**

sufficient data on traditional use of the product

in particular to prove safety

Pharmacological effects / efficacy plausible on the basis of long-standing use and experience

## Key elements of the new EU legislation

**Simplified procedure for access to the market:**

**Labelling / Package leaflet (Article 16g)**

***statement that***

the product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use and

the user should consult a doctor or qualified health care practitioner if the symptoms persist during the use of the product or if adverse effects not mentioned in the package leaflet occur

## Key elements of the new EU legislation

**Simplified procedure for access to the market:**

**Labelling / Package leaflet (Article 16g)**

A Member State may require to mention the nature of the tradition in question

## Key elements of the new EU legislation

**Committee for Herbal Medicinal Products**

**Article 16h**

25 Members / 25 Alternates from all Member States chosen on the basis of their specific scientific competence

max. 5 additional co-opted Members if additional specific scientific competence is needed; chosen among experts nominated by Member States or EMEA

Members may be accompanied by Experts

Legal status identical to other EMEA scientific committees

## Key elements of the new EU legislation

**Committee for Herbal Medicinal Products**

The Committee for Herbal Medicinal Products shall

- at the request of a MS draw up an opinion on the adequacy of the evidence of the long-standing use
- after referral of a MS draw up a Community monograph on traditional herbal products used < 15 years within the Community
- be involved in MR for traditional herbal medicinal products registered on the basis of EU monographs or EU listings

## Key elements of the new EU legislation

**Committee for Herbal Medicinal Products**

The Committee for Herbal Medicinal Products will prepare:

**Article 16f**

- A list of traditional herbal drugs/-preparations/combinations that can be used for the registration procedure (replacing expert report on safety and documentation of traditional use)

## Key elements of the new EU legislation

**Committee for Herbal Medicinal Products**

**Article 16h**

The Committee for Herbal Medicinal Products will prepare

- Monographs on herbal drugs/-preparations that may be used for full marketing authorisations of well-established herbal medicinal products (replacing bibliographic documents) or simplified registrations of traditional herbal medicinal products

## Key elements of the new EU legislation

**Committee for Herbal Medicinal Products**

**Article 16h**

The Committee for Herbal Medicinal Products will

- be responsible for arbitration/referral procedures originating from different views among Member States on nationally authorised herbal medicinal products
- give an opinion on other medicinal products containing herbal substances for human use referred to the EMEA

## Key elements of the new EU legislation

**Committee for Herbal Medicinal Products**

**Article 16h**

The general provisions of the proposed Regulation relating to the Committee for Human medicinal products shall apply by analogy to the Committee for Herbal Medicinal Products

## Key elements of the new EU legislation

**Follow up**

**Article 16i**

A report from the Commission to the European Parliament and to the Council, addressing the possible extension to other categories of medicinal products is required three years after date of entry into force (approx. April 2007)

## Key elements of the new EU legislation

**Implementation**

**Member States and EMEA**

**Article 2**

1. Member States shall comply by (18 months after entry into force; i.e. approx. September 2005)
2. Member States: Traditional herbal medicinal products already on the market: 7 years after entry into force; i.e. approx. April 2011

## Key elements of the new EU legislation

**EMEA**

**Review of Regulation 2309/93 EC**

**TITLE IV**
THE EUROPEAN MEDICINES AGENCY - RESPONSIBILITIES AND ADMINISTRATIVE STRUCTURE
**Article 56**

1. The Agency shall comprise:
(a) the Committee for Medicinal Products for Human Use,
...
(d) the Committee on Herbal Medicinal Products;

## Key elements of the new EU legislation

EMEA

Article 56 (cont.)

(e) a Secretariat, which shall provide technical, scientific and administrative support for the committees and ensure appropriate coordination between them:

....

2. The committees referred to in paragraph 1(a) to (d) may each establish standing and temporary working parties.

Each committee shall establish a standing working party with the sole remit of providing scientific advice to undertakings.

## Key elements of the new EU legislation

EMEA

Review of Council Regulation 2309/93 EEC

TITLE IV, Article 57

The Agency through its committees shall

i) upon request provide technical and scientific support to the Community, Member States, international organizations

m) advise undertakings on the conduct of tests and trials in quality, safety, efficacy

## Key elements of the new EU legislation

EMEA

Review of Council Regulation 2309/93 EEC
TITLE IV, Article 57

The Agency through its committees shall

o) on request by the Commission, give an opinion on products and starting materials

## Key elements of the new EU legislation

EMEA

Review of Council Regulation 2309/93 EEC
TITLE IV, Article 59

In case of any fundamental scientific conflict with any other EU agency or scientific committee a joint document has to be prepared and submitted to the Commission Guidelines

## The Future Committee on Herbal Medicinal Products

Review of Council Regulation 2309/93 EEC
Article 64, paragraph 3

Each year the Executive Director shall submit a draft ***report covering the activities*** of the Agency in the previous year and a draft work programme for the coming year ... making a distinction between ... activities concerning medicinal products for human use, ***those concerning herbal medicinal products*** and those concerning veterinary medicinal products ..

## The Future Committee on Herbal Medicinal Products

Review of Council Regulation 2309/93 EEC
Article 64, paragraph 3

The draft report ... shall include information about the number of applications ..., the time taken for the ..evaluation and the medicinal products authorised, rejected or withdrawn.

## Key elements of the new EU legislation

**EMEA**

**Review of Council Regulation 2309/93 EEC**

**TITLE IV**
**Article 77**

The Commission may, in agreement with the Management Board and the relevant Committee, invite representatives of international organizations as observers.

## Key elements of the new EU legislation

**EMEA**

**Review of Council Regulation 2309/93 EEC**

**TITLE IV**
**Article 78 (2)**

The committees and any working party shall in general matters establish contacts, on advisory basis, with parties concerned ... in particular with patient organizations and health care professional organizations

## Key elements of the new EU legislation

**EMEA**

**Review of Council Regulation 2309/93 EEC**

**Article 89**

This Regulation (Title IV) shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

**April 2004**

## The Future Committee on Herbal Medicinal Products

*Next steps*

EMEA must develop rules of procedure for the different obligations of the new Committee

EMEA must guarantee sufficient organisational/secretarial support

Nomination of delegates, alternates and experts by Member States

National agencies should identify clear responsibilities for decisions and allocate resources for a timely and high-level scientific input in activities, e.g. as rapporteur

## Perspectives for Herbal Medicinal Products

**European Union**

**Consolidation of the legal framework**

- adaptation of requirements and procedures to the situation of herbal medicinal products
- three types of documentation (new tests and trials, bibliographic, traditional use) and two procedures (marketing authorization, trad. registration)
- new Committee with specific expertise and increased reliability of decisions

## Perspectives for Herbal Medicinal Products

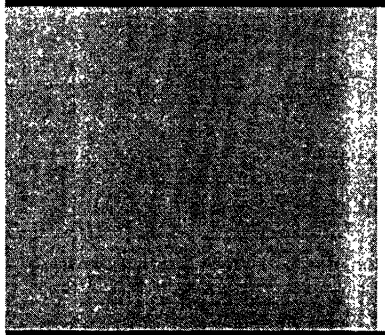
**European Union**

**Consolidation of the legal framework completed by**

- legal definition of food supplements
- legal definition of health claims for foods

# 附錄五

# GCP inspections in Europe



*Agence française de sécurité sanitaire des produits de santé*

afssaps

**Pierre Henri Bertoye, France**

# GCP inspections in Europe

afssaps

1. Regulatory framework

2. Programs

3. Development and harmonisation

# GCP inspections in Europe

afssaps

- **GCP**
  Protects patients/subjects
  - who will participate in clinical trials
  - who are participating in clinical trials
  - who will be treated with marketed medicinal products

1

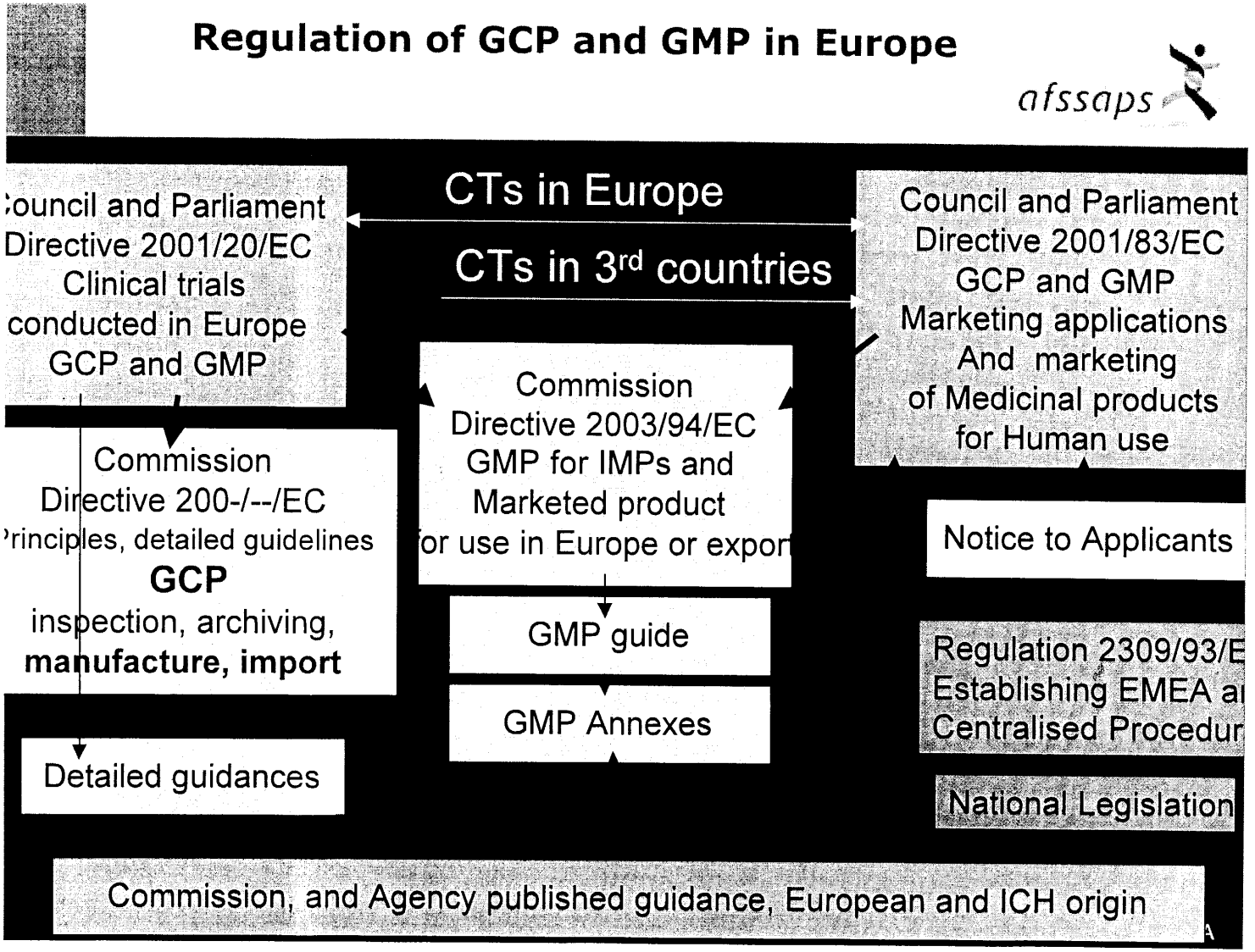
afssaps

# GCP issues : regulatory framework

# 1 GCP issues : regulatory framework

afssaps

- Directive 2001/20/EC – clinical trials
- Directive 2001/83/EC – Code for human medicinal products ; Mark. Authorisation


Regulation of GCP and GMP in Europe
afssaps
Council and Parliament
Directive 2001/20/EC
Clinical trials
conducted in Europe
GCP and GMP
CTs in Europe
CTs in 3rd countries
Council and Parliament
Directive 2001/83/EC
GCP and GMP
Marketing applications
And marketing
of Medicinal products
for Human use
Commission
Directive 200-/--/EC
Principles, detailed guidelines
GCP
inspection, archiving,
manufacture, import
Commission
Directive 2003/94/EC
GMP for IMPs and
Marketed product
for use in Europe or expor
Notice to Applicants
GMP guide
GMP Annexes
Regulation 2309/93/E
Establishing EMEA a
Centralised Procedur
Detailed guidances
National Legislation
Commission, and Agency published guidance, European and ICH origin

## Directive 2001/20/EC on clinical trials
## Objectives

afssaps

A. Setting up a *regulatory level* for :

GCPs
GMPs for Investigational Medicinal Products (IMPs)

And their inspection

B. Defining principles for *protection and rights* of subjects

C. Defining *procedures* and *time frames* **for the** main :

steps
events of the initiation and the conduct of the trial

## Directive 2001/20/EC on clinical trials
## Timetable

afssaps

- Came into force when published 1 May 2001 in Official Journal (L121 pp34-44)
- Member States had until 1 May 2003 to transpose into National Legislation
- That National Legislation has until 1 May 2004 to come into force

## Directive 2001/20/EC on clinical trials
## Inspection

afssaps

- Article 2 Definitions:

(l) "inspection": the act by a competent authority of conducting an official review of, documents, facilities, records, quality assurance arrangements, and any other resources that are deemed by the competent authority to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's site and/or contract research organisation's facilities, or at other establishments which the competent authority sees fit to inspect;

## Directive 2001/20/EC on clinical trials
## Inspection

afssaps

- Article 15, Verification of compliance of investigational medicinal products with good clinical and manufacturing practice practice
  - Inspectors appointed by Member States
  - Inspections Conducted by the Member States Inspectorates
  - Conducted on behalf of the community
  - Inspection results recognised by other Member States
  - Coordinated by Agency in context of Centralised procedure

## Directive 2001/20/EC on clinical trials
## Inspection

afssaps

- Article 15 continued
  - Reports available to sponsor (respecting confidentiality) and on reasoned request to other MS, Agency and IEC
  - Possibility of inspection in third countries

afssaps

## Directive 2001/83/EC of the European Parliament and of the Council

## On the Community code relating to medicinal products for human use

- Marketing authorization
  - Annex 1 amended by Directive 2003/63/EC
- Manufacture and importation
- Pharmacovigilance

afssaps

# Directive 2001/83/EC of the European Parliament and of the Council

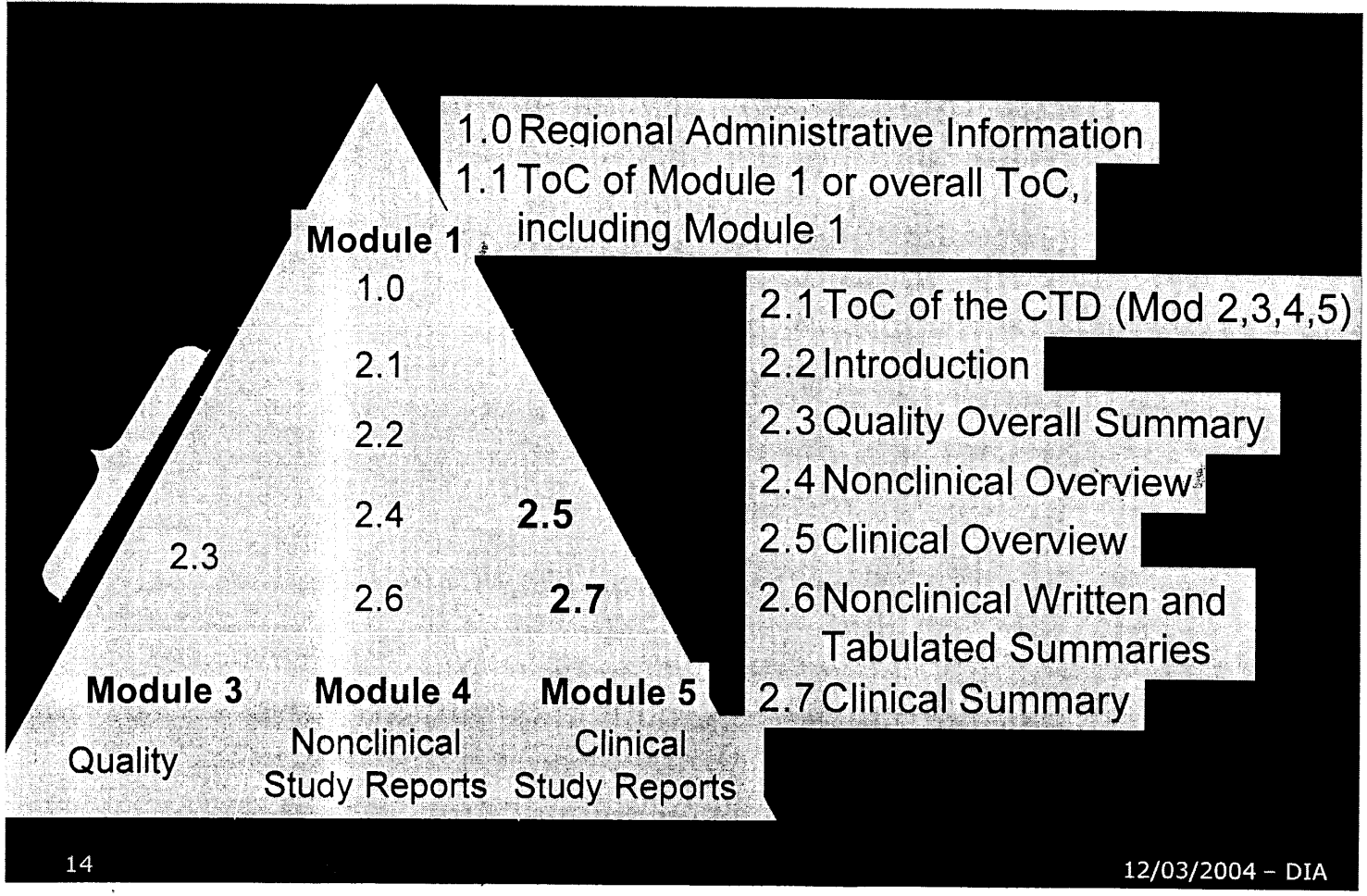
## Marketing authorisation Annex 1 part

- **CONDUCT OF TRIALS**
  - Good Clinical Practice – compliance with Directive 2001/20/EC in Europe or equivalent standards outside of community
- **ARCHIVING – MAH, sponsor, investigator**
- **PRESENTATION OF RESULTS**

**N.T.A. ; CTD**

# N.T.A. – C.T.D

afssaps



2

afssaps

# Inspection programs

## Inspection - context

afssaps

- Ongoing clinical trials and of sponsor/CRO systems
- Trials included in marketing authorization applications (Centralised procedure, Mutual recognition, National)
- Post authorization: pharmacovigilance, phase IV studies, studies conducted as part of specific obligations or follow-up measures

2

# Inspection programs

afssaps

- **Objective 1 : protection of persons undergoing biomedical research in the considered country**
  - **CONTROL OF COMPLIANCE WITH CURRENT LOCAL REGULATIONS**
    - regulations on clinical trials, with GCPs
    - regulations on medical and clinical practice
      - National program for M.S.

2

# Inspection programs

afssaps

- **Objective 2 : Protection of patients who will undergo treatment after marketing approval**

- **CONTROL OF THE CREDIBILITY AND THE QUALITY OF DATA**

  **submitted in the application**

- 'Evaluation' program

# Inspection within the evaluation context

afssaps

## 1 question about Protection of patients

1. Was the protection of patients ensured ?

# Inspection within the evaluation context

afssaps

## 6 questions about quality of data

1. Are the included patients the same as those planned ?
2. Are the treatment groups comparable (still among the study course) ?
3. Were treatments adequately administered ?

# Inspection within the evaluation context

afssaps

## 6 questions about quality of data

4. How was the quality of the data collection (efficacy/safety) ?

5. How were the data handled and analyzed ?

6. Have adverse reactions been reported systematicly ?

# Inspection within the evaluation context

afssaps

## GCP Inspection and the centralised procedure

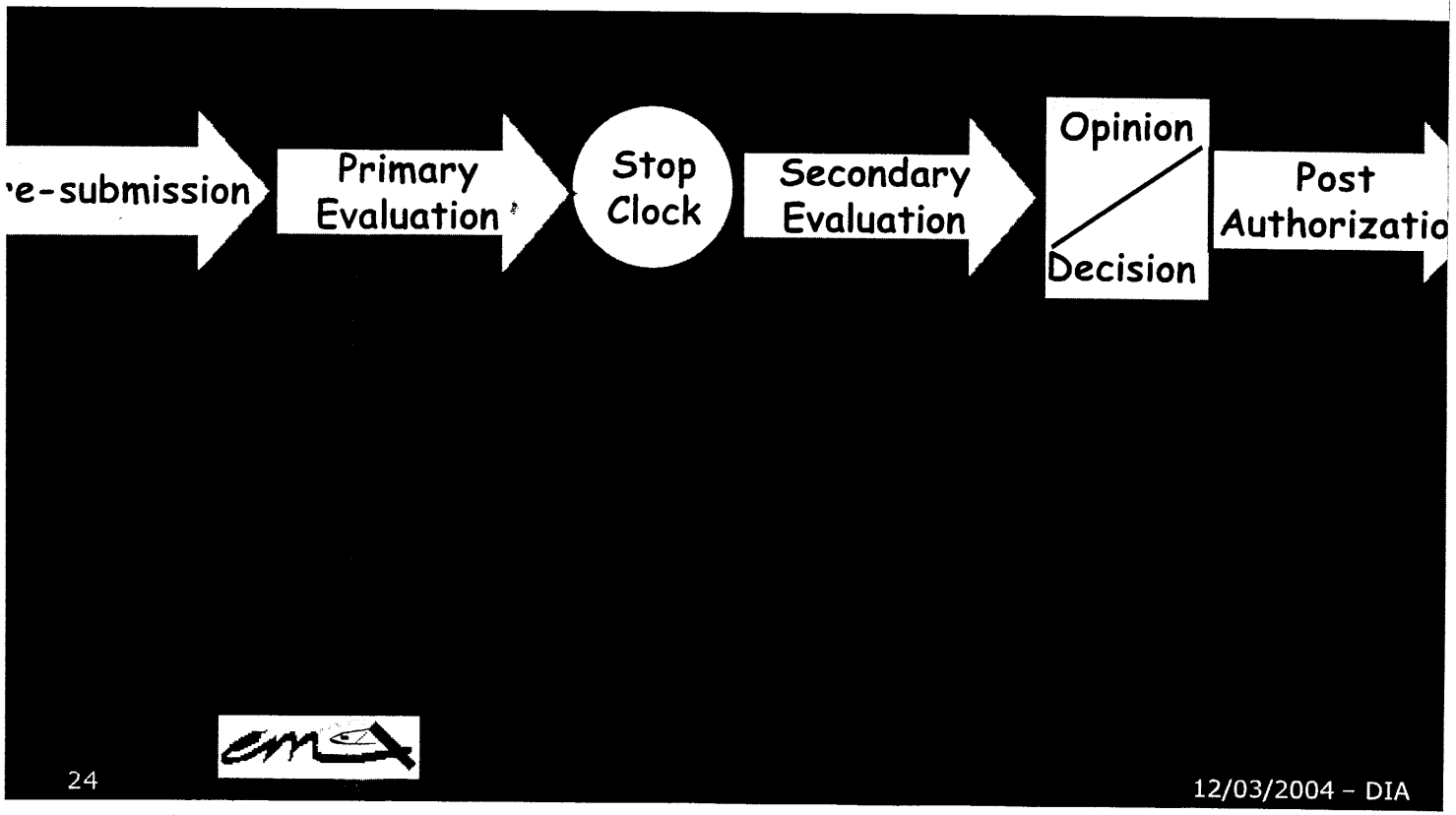
## GCP Inspection and the centralised procedure

afssaps

**Council Regulation 2309/93,** laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products

art 51...the Agency shall undertake the following tasks within its Committees:
e) Co-ordinating the verification of compliance with the principles of good manufacturing practice, good laboratory practice and good clinical practice

# Overview of Centralised Evaluation Procedure



## Reasons for CPMP inspections

afssaps

- **Potential triggers for inspections:**
  - routine surveillance/random
  - targeted
  - issues identified by assessors or other information
  - cause for concern

## Timing of inspections and inspection requests

afssaps

- **Pre-authorization inspections**
  - CPMP adopts request Day 90 or 120
  - Applicant informed in 5 working days
  - Inspection conducted in parallel with clock-stop
  - Individual site reports sent to inspectee – 15 days to respond
  - Integrated report submitted to EMEA/CPMP by day 150
- **Answers to lists of questions may give rise to inspection requests**

## Post-authorisation Inspection

afssaps

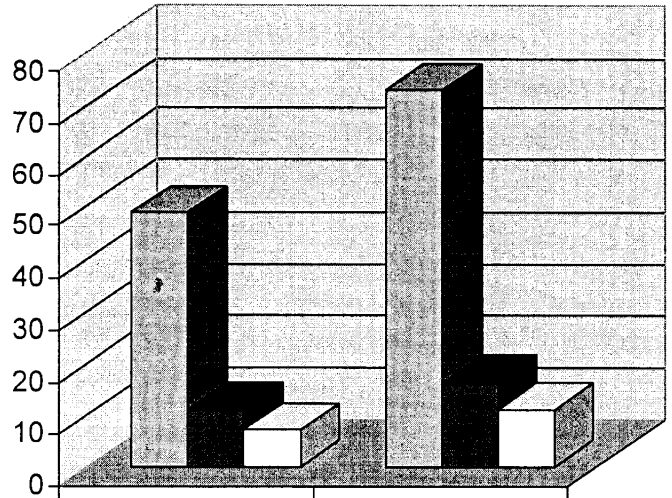
- **Pharmacovigilance**
  - For cause
  - Surveillance
  - System focussed – global and local organisation

- **GCP inspection requests may occur in relation to specific obligations, line extensions, new clinical data/issues**

## Potential Consequences

- **Positive outcome / pointers for future improvement**
- **Negative outcome –**
  - Consequences for ongoing clinical trials or for the application or marketing authorisation
    - Refusal or suspension of all or part of an application
  - Consequences for individual sponsors, investigators, CROs or other involved parties/facilities
    - Curtailment of participation in clinical trials, civil or criminal prosecution – competent authorities enforcement responsibilities

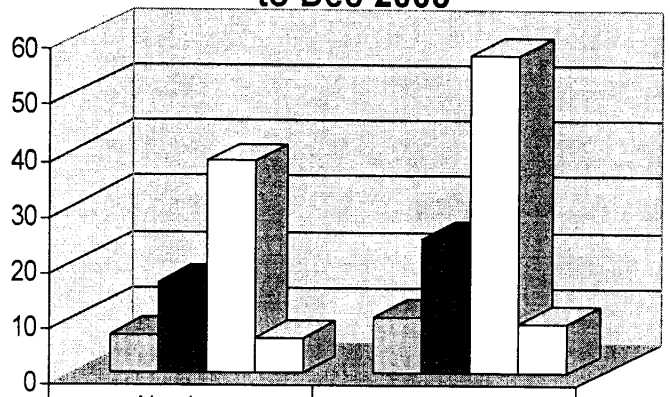
## Centralised Procedure GCP INSPECTION BY AUTHORIZATION PHASE to Dec 2003




| | Number | Percentage % |
|---|---|---|
| Pre Authorisation | 49 | 73 |
| Post Authorisation | 11 | 16 |
| Post Authorisation Pharmacovigilance | 7 | 11 |

afssaps

## Centralised Procedure GCP INSPECTION PER TYPE OF SITE to Dec 2003




| | Number | Percentage % |
|---|---|---|
| Pharmacovigilance | 7 | 10 |
| Sponsor/CRO | 16 | 24 |
| Investigator | 38 | 57 |
| Laboratory/Technical | 6 | 9 |

## Countries involved

afssaps

- CAP inspections have so far involved inspectorates of 12/15 Member states
- Have taken place in 11 Member States, 3 Eastern European countries, Switzerland and USA

3

afssaps

# Harmonisation of inspections et exchange of information

## Development and harmonisation

afssaps

# Harmonisation and expertise through practical action and communication

- **Implement common Policy and Procedures**
- **Development of inspection strategy**
- **Share experience**
- **Shared inspections :** inspection multistate on most Centralised inspections and a number of national/MR inspections
- **Exchange of information**
- **Training**

afssaps

# GCP inspectors:

- EU Member States
- EEA
- CADREAC observers
- Switzerland observer
- As of June 2003, accession countries of May 2004 invited to all meetings

## GCP Inspection Services Group

afssaps

- Meet 4x per year since 1997
- 2-3 day meeting
- Two one day meetings per year with CPMP/assessors/PhvWP/EWP
- Develop procedures for inspection of centralised products
- Present and discuss inspection findings
- Present and discuss grading of findings and potential consequences

# • Development of procedures

- Coordination of inspections
- Preparation of inspections
- Reporting of inspection, including grading of findings
- Inspection records
- Sponsor/CRO, investigator, laboratory, drug safety/pharmacovigilance,
- Computer systems, phase I

# •Development of documents for Directive:

- Article 13 (GMP) in conjonction with GMP inspectors
- Article 15 (Inspection procedures, Qualifications of inspectors, TMF and Archiving)

# •Training

- Special topics during regular meetings
- Dedicated 3 day courses Oct 2001, Oct 2003 involving EU, EEA, Accession countries, additional Eastern European countries and Switzerland

# 附錄六

# FDA GCP Update

David A. Lepay, M.D., Ph.D.
Senior Advisor for Clinical Science and
U.S. Food and Drug Administration
March 12, 2004

## Contents

- FDA GCP Inspections
  - Background and Metrics
  - Emerging Issues
- FDA GCP Program
  - Acceptance of non-U.S. Studies/Data
  - GCP Strategies, Policies, and Guidance

# FDA History in GCP Inspecting

- Early clinical investigator inspections (1962)
- Bioresearch Monitoring Program (1977)
- IRB Inspections (from 1978)
- International clinical investigator inspections (from 1980)
- Comprehensive, cumulative, and multinational program experience

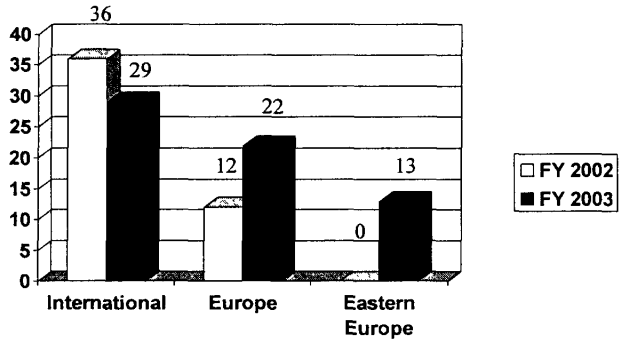
## FDA CI International Inspections*

| | | | | | |
|---|---|---|---|---|---|
| Algeria** | 1 | Germany | 37 | Panama | 1 |
| Argentina | 9 | Greece | 2 | Peru | 4 |
| Australia | 5 | Guatemala | 2 | Philippines | 1 |
| Austria | 5 | Hong Kong | 3 | **Poland** | **8** |
| Bahamas | 1 | **Hungary** | **6** | Portugal | 2 |
| Belgium | 16 | Ireland | 1 | **Romania** | **1** |
| Brazil | 6 | Israel | 4 | **Russia** | **11** |
| Canada | 107 | Italy | 27 | **Slovenia** | **1** |
| Chile | 1 | Japan | 3 | South Africa | 18 |
| China | 2 | Kenya | 1 | Spain | 14 |
| Costa Rica | 5 | **Latvia** | **3** | Sweden | 26 |
| **Czech Republic** | **3** | **Lithuania** | **1** | Switzerland | 1 |
| **Croatia** | **2** | Malawi | 1 | Taiwan | 1 |
| Denmark | 8 | Mexico | 8 | Thailand | 1 |
| Dominican Rep. | 1 | Netherlands | 19 | U. K. | 78 |
| Egypt | 1 | New Zealand | 3 | Venezuela | 2 |
| **Estonia** | **1** | Nigeria** | 1 | Zambia | 1 |
| Finland | 13 | Norway | 3 | | |
| France | 39 | | | | |
| Gabon | 1 | | | | |

*Conducted for FDA/CDER from 1980 through 12/31/03, total 523

**data reviewed in U S.

## CI Inspections - International*




*Conducted for CDER

## International Inspections: Focus

- Outside of the U.S., FDA authority is based on the ability to accept or reject DATA in support of marketing in the U.S.
- Data auditing is therefore a major component of inspections conducted at clinical investigator and sponsor sites
  - Reflects the focus of FDA's application review: ie., on the data itself and on data analyses, NOT on expert reports or summary statements

## International Inspections: Approach

- Whether domestic or international, all FDA GCP inspections are conducted according to the same SOP's (Compliance Programs)
  - Available at www .fda.gov/oc/gcp, link to "Bioresearch Monitoring Program"

## International Inspections: Approach

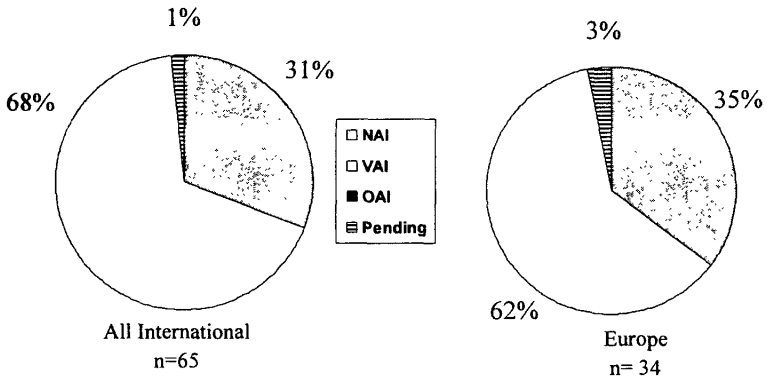
- Inspections all include some attention to:
  - Human subject protection (Consent; IEC Review)
  - Vulnerable populations
  - Compliance with regulations (system audits)
  - Responding to complaints
  - Understanding innovations
  - Education and performance measures

## International GCP: Trends

- Increased expansion of trials to new geographic areas
  - Especially Eastern Europe, Latin America, Asia
- Increased interest and achievements among regulatory authorities in developing GCP regulations and inspectorates
- General improvement in quality and compliance as GCP is formally adopted and implemented

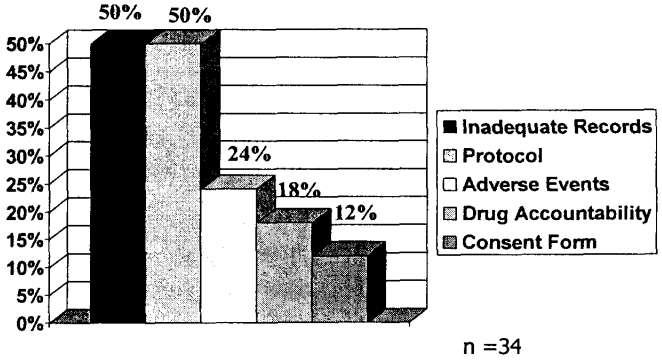
## International Inspection Classifications

FYs 2002-2003



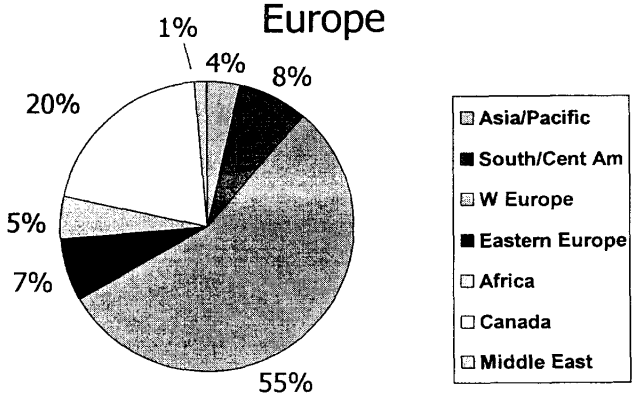
# Clinical Investigator Deficiencies

Europe: FY 2002-2003




n =34

# FDA Experience: Western vs. Eastern Europe



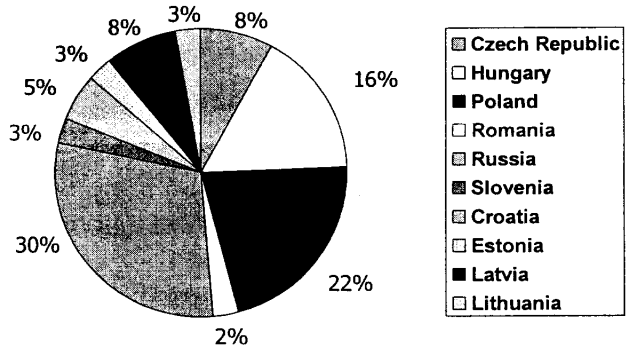

n=523 CYs 1980-2003

## FDA Experience: Eastern Europe

- FDA's earliest inspection in Eastern Europe occurred in Poland (1994)
- But the pace of FDA GCP inspections in Eastern Europe is accelerating
  - 37 inspections since 1994 *
  - 1994-1997: 5 inspections
  - 1998-2002: 18 inspections
  - 2003: 14 inspections

*Calendar Year

## FDA GCP Inspections in Eastern Europe 1994-2003 (by country)




n=37

## GCP Compliance in Eastern Europe

- Quality of FDA-Inspected Sites
  - 1994-1995: 2 VAI, 2 NAI
  - 1996-1998: 4 VAI, 5 NAI
  - 1999-2002: 4 VAI, 6 NAI
  - 2003: 9 VAI, 5 NAI
- To date, no FDA GCP inspection in Eastern Europe has been so violative as to be classified "OAI" ("official action indicated")

## GCP Emerging Issues Worldwide

- Performance: Ensuring Subject Safety and Responsiveness to Problems/Complaints
  - For Cause vs. Surveillance Inspecting
- Investigator-Initiated Studies
- Clinical Investigator Supervision/Delegation
- The Process of Informed Consent
- Ethics Committees: Independence, Operation, Responsibilities, Workload, and Oversight

## FDA GCP Program: Strategies

- Addressing GCP more explicitly in applications to FDA
  - Monitoring plans in higher risk protocols submitted to IND's (e.g., gene therapy)
  - Information on GCP comprehension and compliance in non-IND (international) studies submitted to FDA

## Acceptance of Non-U.S. Studies

- Non-U.S. trials may voluntarily be conducted under U.S. Investigational New Drug (IND) regulations
  - This is rare in practice
  - Requires that all U.S. IND regulations be followed, including:
    - 21 CFR Part 312: IND Regulations
    - 21 CFR Part 50: Informed Consent Regulations
    - 21 CFR Part 56: IRB Regulations

## Acceptance of Non-U.S. Studies

- March 2001: Guidance for Industry, Acceptance of Foreign Clinical Studies
  - Non-U.S., non-IND trials may be accepted for FDA review in support of U.S. marketing if:
    - Trials are acceptable to the U.S. population
    - Well-designed and well-conducted
    - Performed by qualified investigators
    - Conducted according to world ethical principles
    - Subject to FDA Inspection

## Acceptance of Non-U.S. Studies

- March 2001 Guidance
  - Minimal standard: Principles of the 1989 version of the Declaration of Helsinki (Drug/Biologics); Principles of the 1983 version of DOH (Medical Devices)
  - Local Standards (e.g., ICH GCP in ICH regions) if these provide greater protection to subjects

## From the 2001 Guidance

- "FDA is currently reviewing its regulations pertaining to the acceptance of foreign clinical studies to determine if it should revise those regulations to incorporate new or modified standards or requirements"

## Under Consideration –1-

- Moving from vague, non-regulatory language (e.g., DOH) to more explicit reference to GCP
  - ICH GCP (E6): Official FDA guidance
  - FDA is also participating in GCP harmonization efforts for medical devices (ISO) and in working groups with WHO and PAHO

## Under Consideration –2-

- Moving away from just a certification of conformance to some description/ documentation of how GCP standards were met
  - How CI's were trained to comply with GCP
  - How the sponsor monitored the study
  - How informed consent was obtained; what (if any) incentives were provided to subjects
  - Description of the ethics committee, including qualifications of its members

## Also On the Horizon

- IRB Registration
  - Federal Register notice will query whether non-U.S. IRB's should be allowed to register
- (Voluntary, non-governmental accreditation of human research protection programs)
  - Two accrediting bodies in the U.S.
- Guidance on Informed Consent for Non-English Speaking Subjects

## Also On the Horizon

- Safety Reporting Rule
  - Final rule based on review of public comments
- Data Monitoring Committees: Final Guidance
- Financial Interests in Clinical Research
  - DHHS Final Guidance
- Emergency Research Where Informed Consent is Not Feasible: Additional Guidance

## FDA GCP Program: Strategies

- Building on Themes
  - Risk Management
    - Greater risk demands greater attention
    - Examples: Vulnerable subject populations; sponsor-investigators; fraudulent investigators; conflicted financial interests

## FDA GCP Program: Strategies

- Streamlining
  - Reduce burden where added value can not be established
    - Examples: IRB review of individual, undenominated safety reports from remote sites; repetitive IRB review of multicenter trials beyond local considerations

## FDA GCP Program: Strategies

- Leveraging
  - Share information and increase dialogue with other inspectional authorities (U.S. and international)
  - Contribute to capacity-building for new or proposed GCP inspectorates

## FDA GCP Program: Strategies

- Communication and Access
  - Focal point at FDA for Good Clinical Practice Programs
  - GCP/Clinical Trials website
    - www. fda.gov/oc/gcp
  - GCP queries mailbox
    - gcpquestions@oc.fda.gov

## But FDA Needs Help from the World Research Community

- Educating in GCP
- Paying heed to problems and complaints
- Building capacity
- Communicating
- Seeking and enhancing quality
- Being there and doing it well !!