European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

London, 20 April 2006
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REPORT FROM THE FIRST EMEA WORKSHOP WITH HEALTH-CARE PROFESSIONALS ORGANISATIONS

Meeting Chaired by Noël Wathion, Head of EMEA Human Post-authorisation Unit
EMEA, 28 March 2006

Introduction

The EMEA organised a workshop with representatives from twenty-four European health-care professionals' organisations.

The objectives of this workshop were to reinforce communication with representatives of health-care professionals (HCPs), to consider HCPs' needs and expectations from the EMEA, and to explore their further contribution to EMEA activities.

The workshop also involved representatives from the EMEA and representatives from the three human scientific Committees of the EMEA: the Committee for Medicinal Products for Human Use (CHMP), the Committee for Orphan Medicinal Products (COMP), and the Committee on Herbal Medicinal Products (HMPC). The agenda and the list of participants can be found in Annexes 1 and 2 respectively.

Thomas Lönngren, EMEA Executive Director, welcomed the participants and gave a brief overview of the EMEA achievements since its creation 10 years ago. He highlighted some of the key challenges for the future such as the need to stimulate innovation and drug development, the emergence of new therapies and technologies, and the ageing of the population. All these were put in the context of EU enlargement and globalisation, where EMEA is to play a prominent role.

Involvement of partners and stakeholders is of utmost importance for EMEA in order to get their input on the strategy for the future, as expressed in the EMEA Road Map to 2010 *(EMEA Road Map to 2010: Preparing the Ground for the Future)*, but also to answer to their expectations in terms of information and transparency.

Working in this direction, the EMEA has recently developed a Framework for the interaction with Patients' and Consumers' Organisations *(Framework on the Interaction)*. Building up on this successful model, EMEA looks now towards getting feedback from prescribers on issues related to medicines in clinical practice. The present workshop represents the first and crucial step in this interaction process.

Participants' presentations

The workshop was structured in two sessions. The morning session introduced the EMEA and its three human scientific Committees. The afternoon session gave the floor to the health-care professionals to present different views and proposals for the establishment of interaction with the EMEA.

Noël Wathion, Head of EMEA Post-Authorisation Human Unit, and Chairman of this workshop presented the milestones in the history of the EU regulatory system, as well as the overall EMEA

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objectives, its structure and its partners (see Annex III). The EMEA, a networking decentralised agency, is the result of 40 years of harmonisation in the field of medicinal products. European experts' network brings scientific expertise to EMEA with guarantee of independence and integrity through public declaration of interests. Interactions with all stakeholders are of paramount importance in order to adequately address the challenges resulting from political, legal or scientific development, such as EU Enlargement, Paediatric Regulation or therapeutic innovation (i.e. tissue engineering).

Martin Harvey-Allchurch, Head of EMEA Executive Support Sector, presented the EMEA Transparency and Communication Policy (see Annex III). As early as its creation in 1995, the Agency innovated in terms of transparency by publishing European Public Assessment Reports for all products authorised through the EMEA centralised procedure. Transparency and Communication are a critical priority for the Agency that has to be balanced with the legal obligation to protect commercially confidential information. The new EU pharmaceutical legislation gives EMEA new tools to further improve communication, and also better inform the public, e.g. information on rejected medicines, withdrawals of applications, understandable information, medicines database, etc. Communication and transparency policy, as proposed in the EMEA Road Map to 2010, will take into account all interested parties. EMEA will ensure an adequate level of quality of the information provided (e.g. understandable by public), consistency with that provided by National Authorities, and the appropriate use of effective communication channels.

Daniel Brasseur, Chairman of the Committee for Medicinal Products for Human Use (CHMP) presented the work of the Committee (see Annex III). The CHMP is the EMEA Scientific Committee responsible for providing scientific advice and guidance during the development of new medicines, assessing applications for marketing authorisation and ensuring post-marketing authorisation monitoring. The CHMP has the support of its working parties, which provide guidance on the different aspects of product development, as well as Scientific Advisory Groups in specialised therapeutic area (e.g. oncology, CNS, infectious diseases and diabetes/endocrinology). Their role is to provide recommendations on scientific/technical matters related to products under evaluation. The CHMP also interacts with the other EMEA Scientific Committees; the Committee for Medicinal Products for Veterinary Use (CVMP), The Committee for Orphan Medicinal Products (COMP) and The Committee on Herbal Medicinal Products (HMPC). There are possibilities for enrichment of CHMP activities with external scientific input, which can also be provided by HCPs.

On behalf of Josep Torrent-Farnell, Chairman of the Committee for Orphan Medicinal products (COMP), Jordi Llinares Garcia (EMEA) introduced the Committee (see Annex III). The COMP is mainly responsible for the designation of orphan medicinal products. This designation provides incentive to sponsors to further develop and put on the market orphan products. Claim for orphan designation needs to be substantiated with appropriate scientific justification, and significant benefit to patient will be demonstrated at the time of granting of marketing authorisation. Designated investigational orphan products need to be properly developed with high scientific and ethical standards despite possible specific hurdles like the small number of patients available or the lack of a well-recognised endpoint. Rare diseases represent a specific field where input from all stakeholders, especially HCPs, are of utmost importance to address this unique and challenging paradigm.

Konstantin Keller, Chairman of the Committee for Herbal Medicinal products (HMPC), presented this new Committee, which has been into operation since November 2004 (see Annex III). In 2001, the EU legislation gave the possibility of a "Simplified dossier" for registration of traditional herbal medicinal products. Compared with full marketing authorisation, only expert reports on safety and bibliographical or expert evidence on traditional use are required. However, the competent authority can require any additional test on safety, if any safety concern exists. The data on quality are identical to a full marketing authorisation. The Committee focuses mainly on the assessment of "old" substance for self-medication, and provides general guidance (e.g. Monographs, EU Lists), but does not assess specific applications for a particular medicinal product. Complementary medicines are frequently used and often undeclared by patients. Several studies indicate that less than 5% of (serious) adverse drug reactions related to herbal medicinal products are reported. Therefore, interaction in order to facilitate exchange of information between EMEA and all stakeholders is very important. In this sense, HCPs could very much facilitate the reporting of adverse drug reactions.

Isabelle Moulon, Head of Medical Information Sector presented the EMEA product related information and European database on medicines (see Annex III). Apart from currently available information on medicines (such as the SPC [Summary of Product characteristics], the EPAR and public statements on safety issues), the new regulation requires publication of more information (e.g. Assessment Report for refusal and withdrawal of application of marketing authorisation) and that further information is provided in language understandable to patients and the general public (e.g. EPAR summary). The EMEA Quality Review of Documents group is in charge of ensuring linguistic quality and consistency in all EU languages, in accordance with templates and guidelines (e.g. guideline on summary of product characteristics). Isabelle Moulon also introduced the European Public database on medicines, currently under construction. It will include information on medicines authorised in EU, worded in a comprehensible manner and in all EU languages. As per legal requirement, it will also include product information for the use of medicines in children. A first release to the general public (with products centrally authorised through EMEA) is expected by the end of this year. Ultimately, the database is expected to become a prescribing tool for HCPs and the reference website on medicines for patients and consumers in Europe. HCPs are currently involved in the user group where their input is captured.

Lisette Tiddens-Engwirda, Secretary General of the Standing Committee of European Doctors (CPME – *Comité Permanent des Médecins Européens*) and representative of doctors' organisations at the EMEA Management Board, gave a first presentation from HCPs side, and presented the needs and expectations of HCPs' organisations (see Annex III). The CPME is a EU umbrella organisation representing approximately 2 million European doctors from the EU, Norway, Iceland and Switzerland. Its key objectives are to promote the highest standard of medical training and medical practice and to promote public health within the European Union. CPME considers patient safety as a priority; information to patients is still a key area where further progress is expected. The Luxembourg Declaration on Patient Safety (5 April 2005, http://europa.eu.int/comm/health/ph_overview/Documents/ev_20050405_rd01_en.pdf) has given a significant place to "Patient Safety" in the political agenda of the EU, nationally in the EU Member States and locally in the health care sector. She was of the opinion that there should be a single European, high quality, reliable, easily accessible and understandable source of information, especially with regard to safety of medicines. HCPs constitute in her opinion the major and highly trusted source of information to patients. Looking in this direction, doctors will need to be more aware and more involved in pharmacovigilance activities.

Aage Schultz, Executive Director of the European Society for Medical Oncology (ESMO) made a presentation on how to reinforce or initiate communication between EMEA and Health-Care Professionals' organisations (see Annex III). He shortly introduced his organisation and stressed that the incidence of cancer is raising dramatically, especially in the developing world. Significant differences exist in term of cancer survival even within Europe. EMEA approach for a proactive and interactive dialogue with HCPs was very welcomed. A number of proposals for interaction were given, such as the provision of expertise and the use of organisations' scientific journal or newsletter as a tool for communication and dissemination of information. Dr. Schultz also emphasized the possibility to open dialogue regarding orphan drugs/rare diseases, for which ESMO could specifically contribute. Other suggestions were made such as participation in congresses, provision of continued medical education, website cooperation, etc.

Kim M Fox, President Elect of the European Society of Cardiology (ESC) discussed on where and how Health-Care Professionals can further contribute to EMEA activities (see Annex III). Kim Fox introduced the ESC and stressed its mission, which is to improve the quality of life of the European population by reducing the impact of cardiovascular disease. He noted that ESC and EMEA mission are in fact very close with the exception of ESC focus on the cardiovascular field. The structure of the ESC - with national societies, working groups, experts and guidelines – is also consistent with EMEA working practice and would therefore allow proper interaction. Kim Fox confirmed the relevance of earlier proposals for interaction and stressed some of them, such as the provision of further expertise and contribution to product information, including SPC. More specifically, HCPs could support pharmacovigilance activities and in particular the implementation and dissemination of specific

measures within the Risk Management Plans. Exchanges of input on guidances would also be valuable, especially because he considers that EMEA/CHMP and HCP guidelines are complementary; EMEA/CHMP guidelines concern development of medicines and HCP guidelines are clinical practice recommendations. Kim Fox concluded in recommending that EMEA and HCPs' organisations do have to work together.

General discussion

All participants agreed during the following discussion on the importance to provide adequate information on medicines to health-care professionals. Since health-care professionals currently represent the major source of reliable information to patients, appropriate communication tools to reach them must be put in place. Additionally, many other considerations were made:

European experts

- The participants raised the issue of selection of experts to be involved in EMEA activities, and also asked for details on the assessment of any potential conflict of interest. Experts are selected on 2 different basis: internal experts (member of staff of National Agencies) and external experts (providing input on a case by case basis). EMEA representatives also explained the procedure for reviewing the declaration of interest. (EMEA policy and procedure for handling conflicts of interests, here). According to this procedure, participation of experts is allowed according to predefined criteria. Waiver for participation despite conflict is exceptional, e.g. in the area of new therapies where expertise is rare. HCPs expressed their interest to become a source of experts for EMEA activities. With their network of experts, the HCPs' organisations can identify and advise on the best expertise for any specific area. Such proposal will need to be further progressed with the National Competent Authorities, which are the providers of scientific expertise.

- There is a lack of proper recognition for experts when they become involved in regulatory activities. HCPs were of the opinion that this kind of participation necessitates time and high quality expertise and that it should deserve more incentives, such as recognition for their academic career. Further reflexion was deemed necessary on this aspect, in order to ensure that the Community is bringing the highest level of expertise.

- The EMEA Road Map to 2010 states the objective to strengthen the interaction with academia and learned societies by establishing a EU-wide up-to-date inventory of top quality scientific expertise, by involving them in guidance development, training and discussions on innovative approaches to facilitate medicines development, and, by facilitating the exchange of staff between the EMEA and academia/learned societies.

Information and communication:

- The need to raise the public awareness about the EMEA was highlighted. HCPs were encouraged to take an active role in it through their network. In this sense, training on regulatory aspects was found to be of interest, and EMEA could participate in different congresses and conferences from HCPs' organisations. The launch of EudraPharm could also promote further awareness of EMEA. The participants agreed that the EMEA website should be improved to facilitate accessibility to documents.

- HCPs feedback and involvement will also be valuable on product information, and in particular on the SPC which is annexed to the marketing authorisation of each medicine in EU. There is a need to ensure that HCPs perceive this text as useful and of adequate quality, and HCPs collaboration on this aspect would be of major interest.

International cooperation:

- The participants asked about the scientific advice that EMEA can provide. EMEA/CHMP can provide scientific advice on the development of a new medicinal product, and although it is not mandatory, it is strongly recommended to be followed. EMEA/CHMP may also provide different types of scientific advice, for example, to the World Health Organisation (WHO) in view of marketing of medicinal product in countries outside EU. HCPs offered to be involved in this EMEA task.

- HCPs expressed their interest on the interaction between the EMEA and the FDA. For one and a half year, and through a confidentiality arrangement, EMEA and FDA have exchanged information of scientific interest. This contributes to ensure the best regulatory expertise and to facilitate consistency. Nevertheless, EMEA and FDA depend on different legal framework, and therefore decisions of both agencies are independent.

- HCPs requested clarification on the involvement of the EMEA in the Pharmaceutical Forum. The Pharmaceutical Forum was set up by the European Commission, based on the EU High level group on Innovation and Provision of medicines "G-10" recommendation. It includes representatives from the Member States, the European Parliament and the Commission, and representatives of patients, HCPs, industry and other interested parties. This forum has been set-up to make progress on key medicines issues including, pricing, relative effectiveness and information to patients. EMEA is involved in two of the three related working groups; "Information to Patients" and "relative effectiveness".

Pharmacovigilance:

- Pharmacovigilance was identified as one of the key areas for interaction. Identification of different levels of involvement will need to be further discussed and analysed in future discussions.

Other issues:

- HCPs showed interest in the progress achieved by Patients' and Consumers' Organisations in the field of medicines, and in the role they currently play in EMEA activities, and particularly their involvement as experts at the level of the Committees. They expressed interest to develop a joint health care professional-patient interaction based on a true partnership in treatment.

- HCPs alerted of the low public funding on research and innovation in the field of medicines, and that this responsibility remains mainly within the pharmaceutical industry. EMEA has perceived this fact and acknowledged the need for improving public funding on research activities.

- HCPs expressed their concerns and interest with regard to off-label use of medicines, and in particular in children. The expected paediatric regulation aims to partly solve the situation by promoting the development of products in children and ensuring that paediatric information is given both for old and new products.

- Attendees, acting as representant of their organisation, confirmed their willingness in participating to EMEA activities as proposed during this workshop.

Conclusions and next steps

This workshop constitutes the first step for the interaction between EMEA and HCPs. This interaction will take as a reference the successful model developed for the interaction with Patients and Consumers' Organisations.

The ultimate goal of this interaction is the development of a specific framework for interaction between the EMEA and HCPs' Organisations. It will clearly set up the boundaries of the planned interaction and will define the objectives to be achieved.

The achievement of these objectives and the development of the framework of interaction itself will rely on the creation of a formal Working Party with health-care professionals, which will constitute a unique platform of exchange between EMEA, its scientific Committees and HCPs. The Working Party will be composed of medical doctors, pharmacists and nurses' representatives. In a first phase, apart from general expertise, it will cover the therapeutic areas of the mandatory scope for the centralised procedure (Cancer, Diabetes, AIDS and Neurodegenerative diseases) and paediatry. In a second phase, the possibility to widen the group to other specialities will be considered. Additionally, on a yearly basis a workshop with wider representation could be organised. EMEA will define a set of criteria to be fulfilled by HCPs' Organisations before they can be involved in EMEA Activities.

More specifically, the following areas for interaction were identified:

- Information on medicines. How to better inform HCPs and how to improve the quality of the information provided. Input is expected in particular in the following areas: SPC, EPAR, EudraPharm, Eudravigilance, etc.

- Pharmacovigilance activities (risk communication, risk management plan, etc)

- Involvement in EMEA Scientific committees related activities (guideline preparation, participation as experts in scientific advisory groups-SAGs- etc)

- Involvement of Learned Societies and Academia.

Thomas Lönngren concluded the workshop and thanked all participants for this first valuable contact between EMEA and HCPs. The workshop had met its objectives, since many initiatives were already presented and agreed, which will be undertaken to develop the planned interaction.

Participants were informed that a report from the workshop would be prepared and published in the EMEA website, including all presentations displayed during the session.

ANNEX 1

MEETING AGENDA

European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

London, 27 March 2006
Doc. Ref.: EMEA/124808/2006

EMEA WORKSHOP WITH HEALTH-CARE PROFESSIONALS

Tuesday, 28 March 2006

7, Westferry Circus, Canary Wharf, London E14 4HB
EMEA, Conference Room – 4A

Chairperson
Noël Wathion

AGENDA

MORNING SESSION

09:30 – 09:40 **Welcome and Introduction to the Workshop**
Thomas Lönngren, EMEA Executive Director

09:40 – 09:55 **Presentation of participants**

09:55 – 10:10 **Introduction to the EMEA**
Noël Wathion, Head of Post-Authorisation Human Unit

10:10 – 10:20 **The EMEA Transparency and Communication Policy**
Martin Harvey-Allchurch, Head of Executive Support Sector

10:20 – 10:30 **Questions & Answers**

Introduction to the EMEA Human Scientific Committees and their activities

10:30 – 10:40 **The Committee for Medicinal products for Human Use (CHMP)**
Daniel Brasseur, Chairman of the CHMP

10:40 – 10:50 **The Committee for Orphan Medicinal products (COMP)**
Josep Torrent-Farnell, Chairman of the COMP

10:50 – 11:10 ***Coffee break***

11:10 – 11:20 **The Committee for Herbal Medicinal products (HMPC)**
Konstantin Keller, Chairman of the HMPC

11:20 – 11:40 **Questions & Answers**

Overview of Information available to Health-Care Professionals

11:40 – 11:50 **Product related information and European database on medicines**
Isabelle Moulon, Head of Medical Information Sector

11:50 – 12:15 **Questions & Answers**

12:15 – 13:15 ***Lunch***

AFTERNOON SESSION

Establishing an interaction between the EMEA and Health-Care Professionals Organisations

13:15 – 13:30 **Identification of the Health-Care Professionals' needs and expectations from the EMEA**
Lisette Tiddens-Engwirda, Secretary General of the Standing Committee of European Doctors (CPME)

13:30 – 14:00 **Questions & Answers**

14:00 – 14:30 ***Coffee break***

14:30 – 14:45 **How to reinforce/initiate communication with Health-Care Professionals' representatives**
Aage Schultz, Executive Director of the European Society for Medical Oncology (ESMO)

14:45 – 15:00 **Where and how can Health-Care Professionals further contribute to EMEA activities**
K M Fox, President Elect of the European Society of Cardiology (ESC)

15:00 – 15:45 **Questions & Answers**

15:45 – 16:00 **Conclusions and next steps**

ANNEX 2

LIST OF PARTICIPANTS

London, 17 March 2006
Doc. Ref. EMEA/14869/2006

EMEA WORKSHOP WITH HEALTH-CARE PROFESSIONALS

Tuesday, 28 March 2006

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ANNEX 3

PRESENTATIONS

London, 28 March 2006
Doc. Ref. EMEA/113728/2006

EMEA WORKSHOP WITH HEALTH-CARE PROFESSIONALS

INTRODUCTION TO THE EMEA

Noël Wathion
Head of Post-Authorisation Human Unit

EMEA Workshop With Health Care Professionals

Introduction to the EMEA

Noël Wathion
28 March 2006

30 Years of Harmonisation

- 1965: First Directive laying down basic principles
- 1975: First pharmaceutical testing Directive
- 1981: Specific veterinary legislation adopted
- 1985: "1992 Single Market" project launched
- 1993: Council Regulation (EEC) No 2309/93 adopted
- 1995: EMEA officially opens and new European system comes into operation
- 1998: Reinforcement of the system takes place
- 2001: Review of the system is initiated
- 2004: Enlargement of the EU
- 2004: Implementation of part of new Community legislation
- 2005: Implementation of remainder of new Community legislation

The EU Regulatory System

Objectives

- To complete the single EU market for pharmaceuticals
- To protect and promote public and animal health
- To facilitate access by patients to new & better medicines
- To allow further development of European based R&D pharmaceutical industry
- To provide a platform for discussion of public health issues at European level

The EU Regulatory System

EMEA Mission Statement

In the context of a continuing globalisation, to protect and promote public and animal health by:

- developing efficient and transparent procedures to allow rapid access by users to safe and effective innovative medicines and to generic and non-prescription medicines through a single European marketing authorisation,
- controlling the safety of medicines for humans and animals, in particular through a pharmacovigilance network and the establishment of safe limits for residues in food-producing animals,
- facilitating innovation and stimulating research, hence contributing to the competitiveness of EU-based pharmaceutical industry, and
- mobilising and coordinating scientific resources from throughout the EU to provide high-quality evaluation of medicinal products, to advise on research and development programmes, to perform inspections for ensuring fundamental GXP* provisions are consistently achieved, and to provide useful and clear information to users and healthcare professionals

* GXP means 'good clinical practice' (GCP), 'good manufacturing practice' (GMP) and 'good laboratory practice' (GLP) collectively

EMEA General Information

EMEA Tasks

- Provision of scientific advice and protocol assistance to companies
- Orphan drugs designation
- Evaluation of applications under the centralised procedure
- Management of arbitration and referral procedures
- Coordination of pharmacovigilance activities
- Coordination of Member States' inspections (GMPs, GCPs, GLPs)

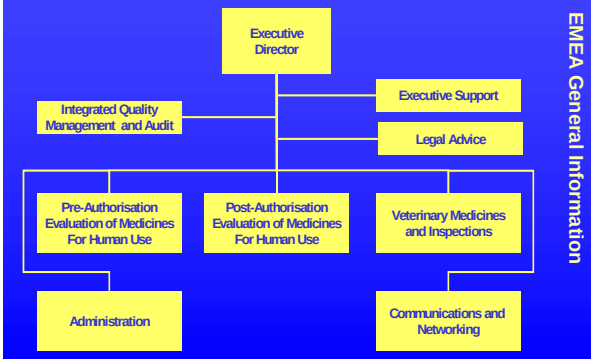
EMEA General Information

EMEA Global Structure

- Management Board
- Committee for Human Medicinal Products (CHMP)
- Committee for Orphan Medicinal Products (COMP)
- Committee for Veterinary Medicinal Products (CVMP)
- Committee for Herbal Medicinal Products (HMPC)
- Permanent Secretariat
- Executive Director

EMEA General Information

Organisation/Structure



EMEA: A Networking Decentralised Agency

- Member States have pooled their sovereignty for authorisation of medicines
- EMEA is designed to coordinate the existing scientific resources of Member States
- EMEA is not intended to replace National Competent Authorities, but to be a partner in the system
- A 'virtual' agency, providing an interface between all partners
- All parties linked by an IT network (EudraNet)

EMEA and Its Partners

- 42 National Competent Authorities (dealing with human and veterinary medicines)
- Network of some 3,500 European experts
- European Commission, European Parliament and other EU Agencies (EMCDDA, Euro-CDC, EFSA)
- European Pharmacopoeia (Council of Europe)
- Medicines Control Laboratories Network

EMEA and Its Partners: National Competent Authorities

- European experts' network underpins the work of the EMEA scientific committees and their working parties
- European experts work for EMEA independently of their nominating authority
- Scientific competence is guaranteed by their nominating authority, independence and integrity assured through public declaration of interests
- Services provided to EMEA on basis of a contract (conditions, quality and payment)

EMEA and Its Partners: EU Institutions

- EMEA is a decentralised agency of the EU, not part of the European Commission
- EMEA adopts opinions on the basis of scientific criteria and the Commission takes decisions based on these opinions, legally binding on all Member States
- European platform for scientific questions

Looking at the Future

- The future for medicinal products requires adequate initiatives to address successfully the challenges the EU Regulatory System will face resulting from political, institutional, legislative and scientific developments
- The EMEA is providing an increasingly important contribution for safeguarding the future of medicinal products
- The EMEA Road Map project describes the initiatives the Agency will undertake in the various fields up to 2010
- Adequate collaboration with all the Agency's partners and stakeholders will be paramount to enable this objective to be met

London, 28 March 2006
Doc. Ref. EMEA/112924/2006

EMEA WORKSHOP WITH HEALTH-CARE PROFESSIONALS

THE EMEA TRANSPARENCY AND COMUNICATION POLICY

Martin Harvey-Allchurch
Head of Executive Support Sector

European Medicines Agency

EMEA transparency and communication policy

Martin Harvey

EMEA workshop with healthcare professionals
28 March 2006

- Agency began in 1995 with a limited but innovative series of obligations to communicate and inform healthcare professionals and patients
- Gradually added new policies over the years
- New legislation in 2004/5 gave EMEA expanded mandate to communicate and inform
- 'Road Map' sets out how we want to implement this new authority and other policies

- Transparency and communication is critical for the European Medicines Agency
- We must not only be independent in our scientific work and the information we provide
- We must also be seen to be independent – and that means being as open and transparent as we can be … but …

- We also have legal obligations to protect commercially confidential information
- The Agency's transparency and communication activities have to strike a balance between our public (and animal) health obligations and legal obligations

- New legislation reinforced EMEA transparency mandate: information on medicines rejected, withdrawal of applications, medicines database, safety data, understandable patient information, explicit authority to establish relations with healthcare professionals and patients
- 'Road Map 2010' proposes a Communication and Transparency Policy, in consultation with all interested parties

- Growing workload v. limited resources
- New legislation with a broader communications mandate
- Competing pressures for faster drug reviews v. safer drugs
- Closer scrutiny of governmental bodies and industry regulators in particular
- Swinging pendulums: How should regulators respond to these competing pressures?
- Changing communication channels (internet, global media, 24/7 news world, better coordinated interest groups)

London, 28 March 2006
Doc. Ref. EMEA/112960/2006

EMEA WORKSHOP WITH HEALTH-CARE PROFESSIONALS

Introduction to the EMEA Human Scientific Committees and their activities

The Committee for Medicinal products for Human Use (CHMP)

Daniel Brasseur
Chairman of the CHMP

EMEA Workshop with Health-Care Professionals

Introduction to the EMEA Human Scientific Committees and their activities (CHMP)

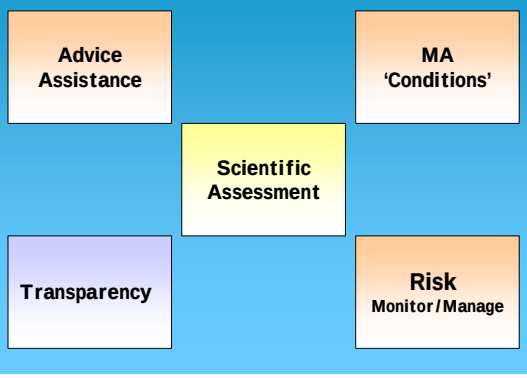
London
March 2006

Daniel Brasseur
CHMP at EMEA

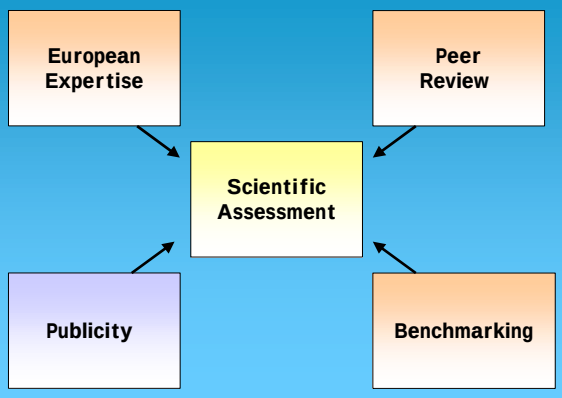
1.

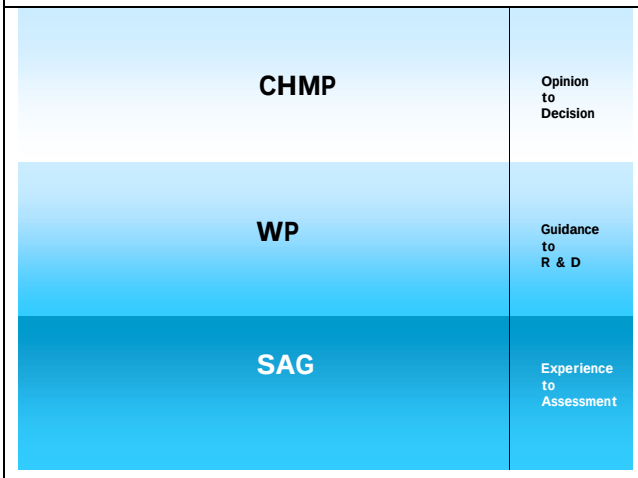
The positioning of the Scientific Committees at the EMEA

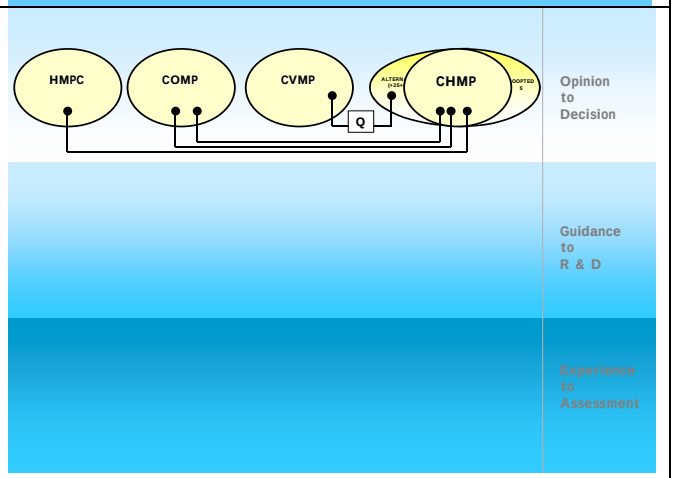
Objectives

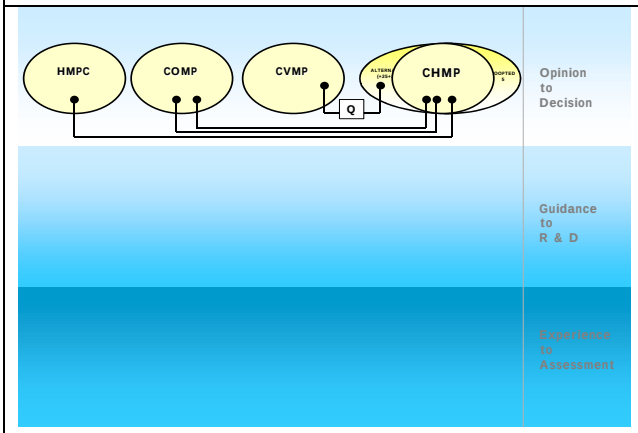


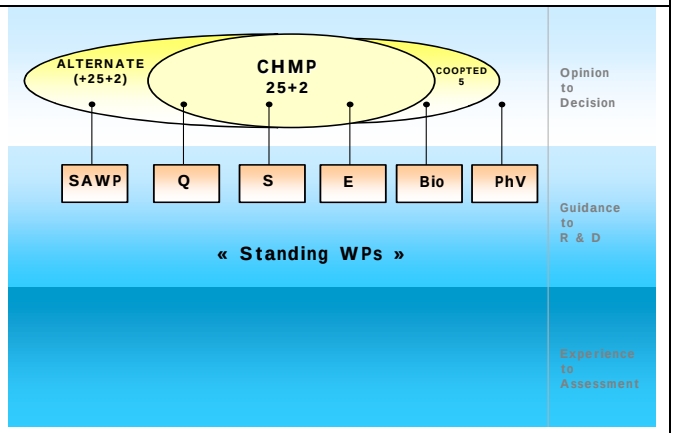
Means

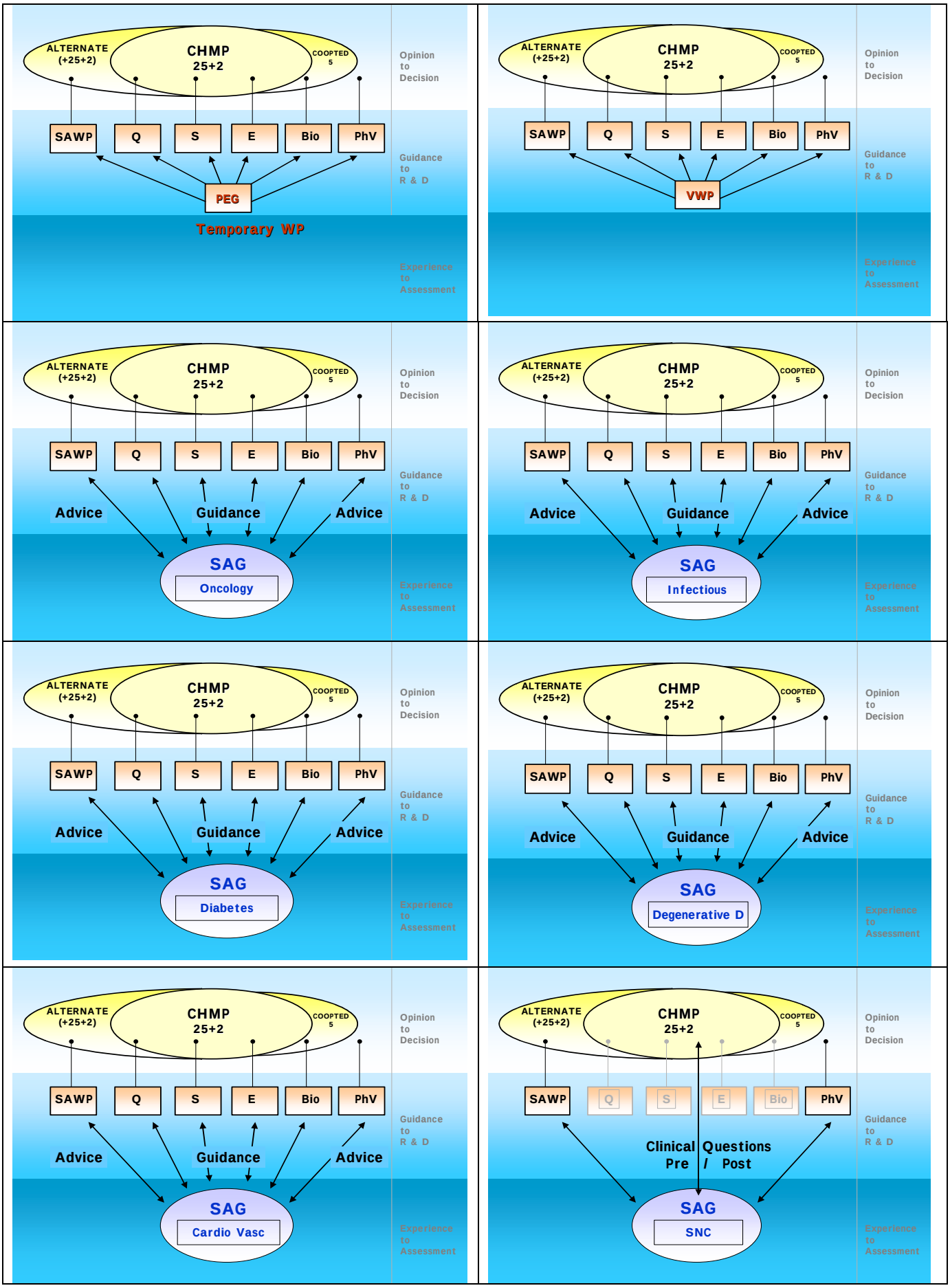


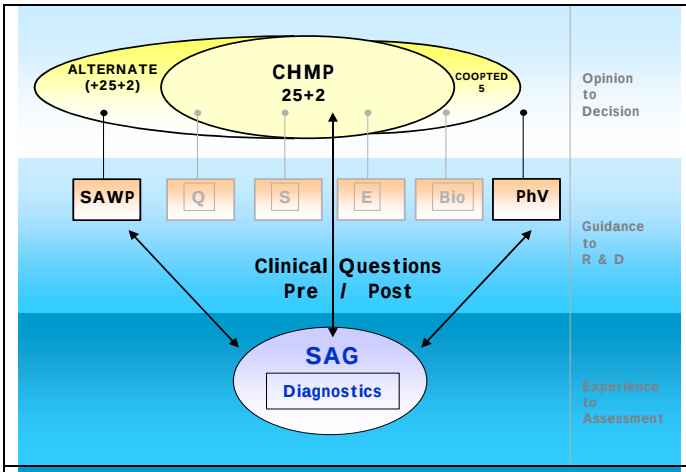


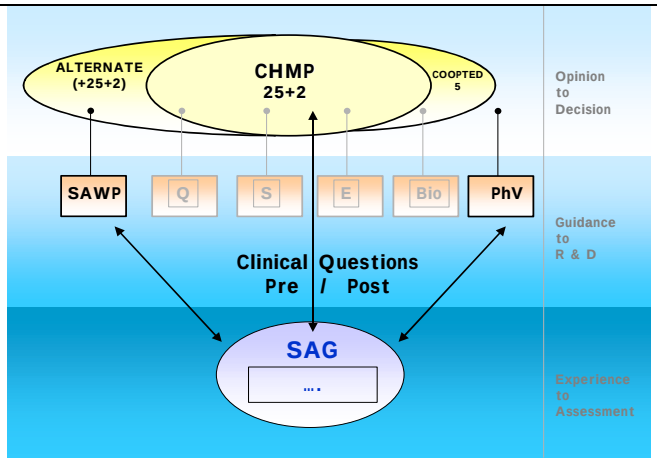







ALTERNATE (+25+2)
CHMP 25+2
COOPTED 5
SAWP
Q
S
E
Bio
PhV
PEG
Temporary WP
VWP
Advice
Guidance
Advice
SAG
Oncology
Infectious
Diabetes
Degenerative D
Cardio Vasc
Clinical Questions Pre / Post
SNC
Opinion to Decision
Guidance to R & D
Experience to Assessment





2.

How to implement Scientific Advice in an optimal time frame?

Procedure

Current SAWP-CHMP Procedure: EMEA "filter" / Validation

Day 0: Appointment of Coordinators

Day 30/40: First Reports

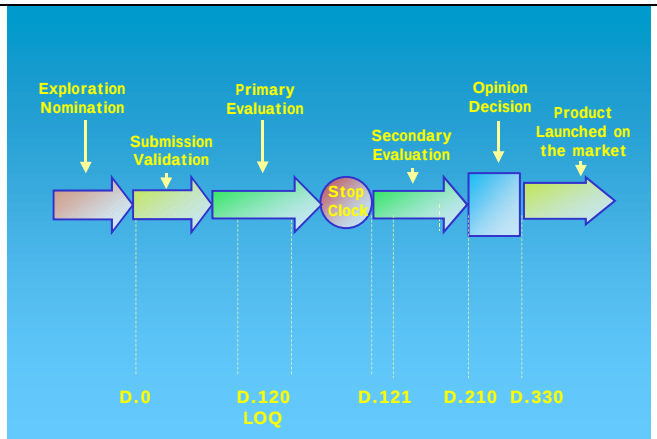
+ Input WP (Discussion or written procedure)

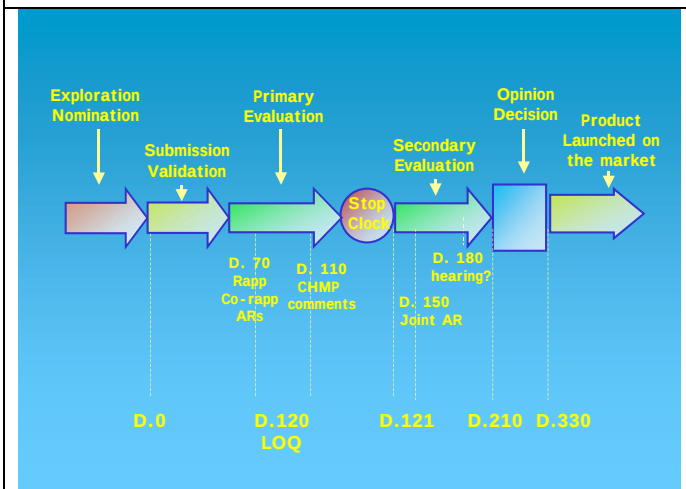
Day 60/70: Discussion meetings & Final Advice

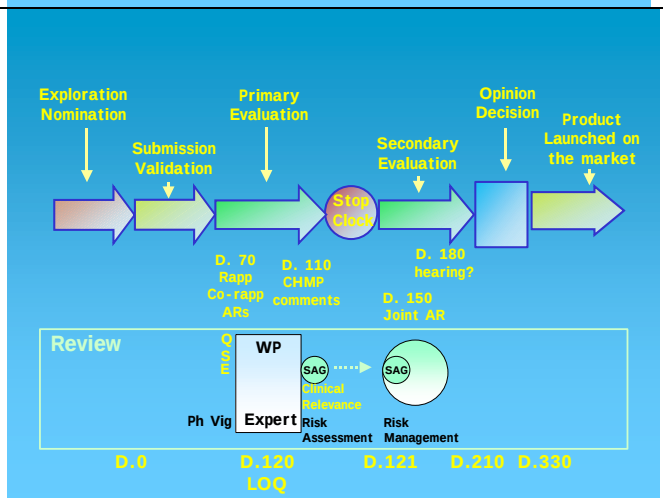
Day 90/100: Final Advice (if necessary)

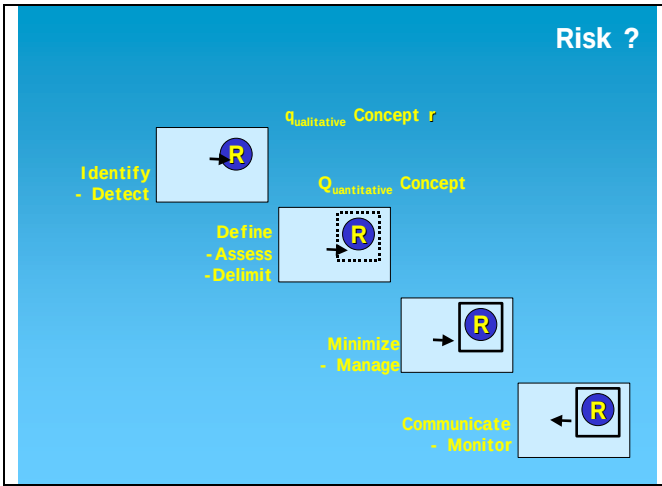
3.

How to enrich the evaluation process with added Scientific Input in an optimal time frame?



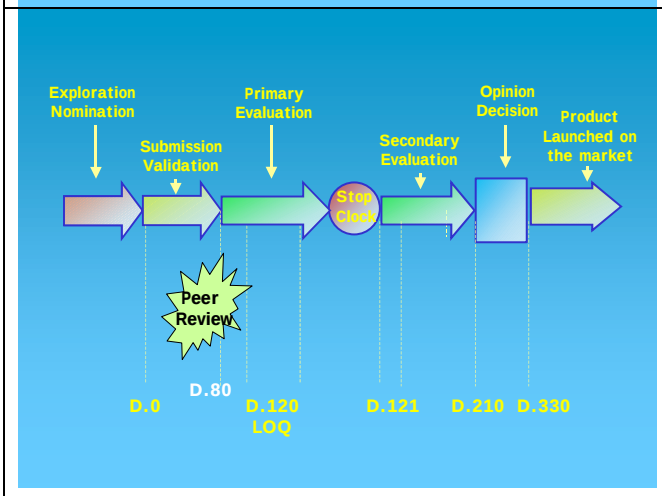






4.

Setting the scientific Standards in the EU
The Peer Review



London, 28 March 2006
Doc. Ref. EMEA/112964/2006

EMEA WORKSHOP WITH HEALTH-CARE PROFESSIONALS

Introduction to the EMEA Human Scientific Committees and their activities

The Committee for Orphan Medicinal products (COMP)

Josep Torrent-Farnell
Chairman of the COMP

EMEA Workshop with Health-Care Professional

THE COMMITTEE FOR ORPHAN MEDICINAL PRODUCTS (COMP)

Josep Torrent-Farnell

Chair, *Committee for Orphan Medicinal Products* (COMP); EMEA, London
Autonomous University of Barcelona

London, 28th of March 2006

INNOVATIVE ORPHAN MEDICINES*

- Timely address unmet medical needs
- Orphan Drug Designation (ODD) provides Community/National incentive to sponsors
- Rare conditions (low prevalence < 1/2000; maximum: 254.000 patients/25 EU)

Designated investigational orphans needs to be proper developed with higher scientific and ethical standards to be transformed into good authorised Orphan Medicines

*Regulation (EC) No 141/2000; Regulation (EC) No 847/2000

TASK OF THE COMMITTEE

- **Scientific evaluation**:
  - Orphan drug designation
  - Protocol assistance (through SAWP)
  - Significant benefit at the time of granting MA
  - 5 years review (economic evaluation upon request from MS)
- **Public health activities**
  - Advice Commission to establishment develop OMP policy
  - Liaising internationally and liaising with patient groups
  - Assist Commission in preparing guidelines
  - EU Experts Network/ Increase visibility

COMP working groups: interested parties, biotech, epidemiological.

COMP collaboration: CHMP, SAWP, PEG, Article 8.2

ORPHAN DESIGNATION CRITERIA

- Identifies 'orphan' products eligible for incentives
- Application from sponsor should demonstrate:
  - → life-threatening or debilitating nature of condition
  - → medical plausibility
  - → prevalence < 5 in 10,000 or unlikely to generate sufficient return on investment
  - → no satisfactory methods exist or medicinal product will be of significant benefit

All claims should be substantiated on appropriate scientific bases

COMP Opinions ➡ EC Designations

ORPHAN MEDICINAL PRODUCTS

Main EU Incentives

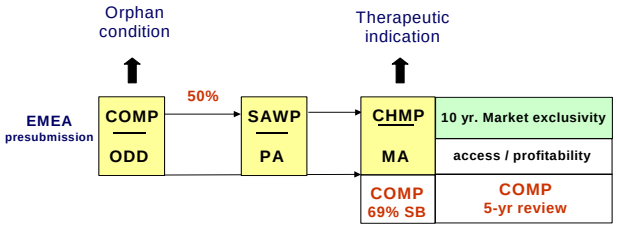
- Ten years exclusivity from the date of marketing authorisation
- Protocol assistance from the EMEA
- Direct access to Centralised Procedure
- Fees reduction for centralised applications
- Priority access to EU research programs

National Incentives

- Inventory published on Commission Web-site

ORPHAN DRUG CONTINUITY POLICY

(From designation to MA and post-authorisation)



uncertainty: very-high high less

ACHIEVEMENTS: ORPHAN DESIGNATION (I) (as March 2006)

- Applications submitted: 563
- Positive COMP opinions: 369
- Commission Decisions 357
- Final negative opinions: 9
- Withdrawals: 159

Success rate: 68%; OOPD / FDA success rate: 62%

Number of applications & quality growing

ACHIEVEMENTS: ORPHAN DESIGNATION (II) (as March 2006)

- Oncology (39%); Immunology (11%)
- 90% low prevalence of less than 3 / 10.000
- 53% novel / innovative products (21% biotech-based / emerging therapies)
- 80 Protocol Assistance finalized by SAWP (40% ↑ 2004 / 2003)
- By population: 48% adults only
  42% adults/paediatric use
  10% paediatric only

MARKETING AUTHORISATION FOR ORPHAN DRUGS*

- Centralised procedures: positive 23 (+2)
  withdrawn 13
  negative 2
  on going 19
- National procedures: 2

→ **Benefiting potentially > 1 millions patients**

- Sponsor's EMEA survey indicates:
  71% (phases II and III)
  58% (seek PA / SAWP)
  50% (plan to file MAA in next 3 yrs.)

→ **Substantial increase of the EMEA workload**

*Mandatory Centralised Procedure as November 2005 (Reg 726 / 2004)

SOME HURDLES ON ORPHAN MEDICINES CLINICAL RESEARCH (I)

- Lack of public awareness ("Invisible diseases")
- Scarcity of Clinical Experts and Reference Centres
- Delays on Diagnosis (Genetic Testing)
- Small size population
- Geographic dispersion
- Life-threatening /chronic debilitating conditions
- Heterogeneous conditions
- Difficult to stratify by stage/severity
- Limited available treatments

SOME HURDLES ON ORPHAN MEDICINES CLINICAL RESEARCH (II)

- Lack of validated biomarkers and surrogate endpoints
- Lack of predictive/validated preclinical models
- Ethical concerns on the use of placebo (e.g. Emerging therapies) and vulnerable population
- Off-label use (medicines for children)
- Participative role of patients to be increased
- Poorly motivated health professionals/investigators
- Lack of information to "care-givers"
- Excessive bureaucratic/administrative barriers

CHALLENGES ON ORPHAN DRUG CLINICAL DEVELOPMENT ("FEASIBILITY CONCEPT")

- Conventional methodological designs need to be adjusted and applied in a flexible manner
- Alternative methodological approaches and patient-saving designs should be encouraged
- Compassionate and expanded access programs should not undermined the conduct of well-designed studies
- Investigation phase goes beyond the MA: conditional / under exceptional circumstances approval, thus early PhV planning and risk-management strategies becomes crucial

« Nice to know v.s. Need to know »

POSITIVE EMEA POLICY TO STIMULATE O.D. RESEARCH

- Promote the use of Scientific Advice/Protocol Assistant Procedures (SAWP)
- EMEA current policy offers 100% fee reduction, this accounts for ensuring the continuity of the EU special budget contribution
- Reinforce the contribution of preclinical and clinical assessors and experts
- Favor and consolidate a progressive input of patients expertise
- Strengthen EMEA/FDA collaboration to underpin a proper global and international research efforts

➡ **EMEA office for SMEs has been recently set up**

IMPROVING CLINICAL DEVELOPMENT SUCCESS RATE

- EMEA long – term sustainability policy & quality work for orphan medicines:
  - Continue the EU Special Contribution (sponsor fee waivers)
- Reinforcing OMP Research through 7th FP /DG research toward a COMP Clinical Research Grant Program ("Budget cut"???)
- Consolidating collaboration and co-ordination with DG SANCO: Rare Disease Task Force
- Encouraging MS to actively adopt national incentives
- Strengthening EMEA/FDA collaboration to underpin a proper global/international efforts.
- Promoting Public-Private Partnership

SO….. RARE DISEASES OFFERS…..

- An unique and challenging clinical paradigm
- Encompasses a wide range of different medical conditions
- Knowledge gather in this setting can be extrapolated in other conventional diseases
- High contribution from patients organisations
- Stimulates creativity and interest of clinicians and academics
- Big-pharma and SMEs may use this opportunity to further develop "personalised" medicines

CREATING A TRUE EU PARTNERING ENVIRONMENT WITH ALL STAKE-HOLDERS

Rare (low-prevalence) diseases are a pan-European challenge that need national solutions

…also…

Rare conditions are a national problem that need EU strong support and policy commitment

Academics' contribution and independent funded clinical and epidemiological research becomes crucial

London, 28 March 2006
Doc. Ref. EMEA/112965/2006

EMEA WORKSHOP WITH HEALTH-CARE PROFESSIONALS

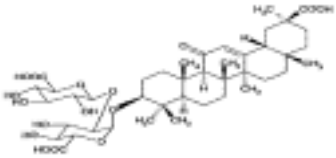
Introduction to the EMEA Human Scientific Committees and their activities

The Committee for Herbal Medicinal products (HMPC)

Konstantin Keller
Chairman of the HMPC

The EU Committee on Herbal Medicinal Products HMPC

Konstantin Keller
Federal Ministry of Health, Bonn



Regulation 726/2004 EC

of 31 March 2004

TITLE IV
THE EUROPEAN MEDICINES AGENCY - RESPONSIBILITIES AND ADMINISTRATIVE STRUCTURE
Article 56

1. The Agency shall comprise:
2. a) the Committee for Medicinal Products for Human Use (CHMP),
   …
   (d) the Committee on Herbal Medicinal Products (HMPC);

EMEA Committee on Herbal Medicinal Products

Inaugural Meeting 23-24 September 2004

Chair / Vice-Chair: Dr. Konstantin Keller / Dr. Heribert Pittner AU

Austria	France	Lithuania	Slovenia
Estonia	Germany	Luxembourg	Spain
Belgium	Greece	Malta	Sweden
Cyprus	Hungary	Netherlands	United Kingdom
Czech Rep.	Ireland	Poland	
Denmark	Italy	Portugal	
Finland	Latvia	Slovak Republic	

4 co-opted Members

EEA Members: Norway, Iceland

Observer: EDQM/Europ. Pharm. Romania; Bulgaria

Mobilizing European Expertise

Appointed by the HMPC

Co-opted members to complete specific expertise:

- clinical pharmacology
  June 2005: Dr. Wissinger-Gräfenhahn, Berlin, DE
- toxicology
  June 2005: Prof. Pelkonen, University of Oulu; FI
- non-clinical/experimental Pharmacology
  November 2005: Prof. Laekeman, University of Leuven, BE
- pediatric medicine
  January 2006: Prof. Widhalm, Vienna Medical University, AU
- Traditional herbal medicine (ongoing)
  (European/Anthroposophic, TCM, Ayurveda)

Herbal Medicinal Products in the EU

Access to the market

New option for access to the market:

Directive 2001/83 EC, Chapter 2a, Articles 16 a – 16 i

Registration

4. "Simplified dossier" for traditional herbal medicinal products

National procedure with limited access to mutual recognition procedure (monograph or list from the HMPC required)

The new simplified registration procedure

Registration of traditional herbal medicinal products
applicable to ***traditional*** herbal medicinal products

Article 16c 1 (c)

medicinal use within the EU throughout > 30 years

or

> 15 years in and > 15 years outside the EU

Deviations may be decided by the Herbal Committee if requested by a Member State

Legal Clarification of Terms

Article 1 of Directive 2001/83 EC as amended by 2004/24/EC

32. Herbal preparation:
preparations obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.

Isolated, chemically defined constituents of medicinal herbs such as Menthole, Eugenole, Digitoxine etc. are not "herbal preparations"!

The new simplified registration procedure

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

The new simplified registration procedure

Directive 2004/24/EC of 31 March 2004

The Committee for Herbal Medicinal Products will prepare:

Article 16f

A list of traditional herbal drugs/-preparations/combinations

Article 16h

Community herbal monographs on herbal drugs or herbal drug preparations that may be used for full marketing authorisations of well-established herbal medicinal products or simplified registrations

Risks associated with Herbal Medicinal Products

Singular effects of the universal vegetable pills in a green grocer, 1834/1835

Examples:

Asteraceae, e.g. Arnica
strong allergic reactions

Hypericum
Phototoxicity, interactions

Kava-Kava
Hepatotoxicity

Aristolochia
Cancer, Nephrotoxicity

Rates of Spontanous Reporting of Adverse Drug Reactions in France

Bégaud B, Martin K, Haramburu F, Moore N
JAMA 288: 1588 (October 2, 2002)

Analysis of 3 studies in France

Conclusions

" … No more than 5 % of serious Adverse Drug Reactions were reported …"

Trends in Alternative Medicine Use in the US 1990-1997

Eisenberg et. al. JAMA 280:1569-1575 (1998)

Patients using herbal medicines / megavitamins *concurrently with prescription medicines* estimated:

15 Million (18.4 % of all prescription users)

39.8% of alternative therapies were disclosed to physicians

46.0% of alternative therapies was done without any input from a medical doctor or alternative practitioner

Potential health risks of complementary alternative medicines in cancer patients

Werneke U et al. (2004) Brit Journal of Cancer 90:408-413

318 cancer patients

51,6 % used Complementary / Alternative Medicines

of patients using

10,4 %	only herbal medicines (Echinacea > Oenothera >> Ginkgo > Silybum)
47,6 %	herbal and other CAM

11 % of the patients exceeded the recommended dose of CAM

Undeclared use of Hypericum preparations in hospitalized patients

Haefeli WE et al. (2004) Brit J Clin Pharmacol 58:437-441

150 Patients enrolled (47 F, 103 M; 60 +/- 13 years)

12 (8%)	positive for Hyperforin or Hypericin
11/12 (92%)	did not inform the medical team
9/12 (75%)	did not inform the research team (medical team and pharmacist)

7/12 (58%) patients used other medication dependent from p-glycoprotein transport or CYP 3A4 metabolism

Different standards for reporting ADRs to herbal remedies and conventional OTC medicines: Interview with 515 users

Br. J. Clin Pharmacology 1998, Vol. 45: 496-500

Consumers' Reaction to Adverse Drug Reactions

	no for OTC yes for herbal	yes for OTC **no for herbal**
Consult GP (serious* ADR):	0,8%	**26.0%**
Consult GP (minor** ADR):	0.4%	14.6%

*serious = "worrying or alarming"
**minor = "some discomfort"

ADRs to herbal medicinal products Interview with 1044 women

Eur. J. Clin Pharmacology 2006, Vol. 62: 37-42

Outpatient population in an Italian university hospital

47 % used at least one herbal compound within 12 months

9.6 % of users reported adverse events (AE):

- gastro-intestinal (dandelion, fennel, propolis)
- cardiovascular (liquorice, ginseng, green tea)
- dermatological (propolis, thyme, arnica, passionflower)
- neurological (guarana, liquorice)

10.6 % of AE resulted in hospital admission

61.7 % of AE were not communicated to the doctor

Summary

- **The HMPC is operational since November 2004**
- **Comprehensive set of guidance already available**
- **HMPC activities differ from CHMP / COMP:**
  - Focus on assessment of substances / general guidance (e.g. Monographs, EU List)
  - No application / applicant that could be charged with fees
  - Focus on "old" substances and on self-medication
- **Co-operation and dialog within EMEA and with other EU bodies, stakeholders and Member States needed**

London, 28 March 2006
Doc. Ref. EMEA/112969/2006

EMEA WORKSHOP WITH HEALTH-CARE PROFESSIONALS

Overview of Information available to Health-Care Professionals

Product related information and European database on medicines

Isabelle Moulon
Head of Medical Information Sector

Product related information & European database on medicines

Isabelle Moulon

Background

- Regulation (EC) 726/2004: Articles: 3-11-12-13-14-20-22-26-57-59-83
- Transparency measures adopted by the Management Board
- EMEA Road Map to 2010

Which information is already available?

Initial application:

- CHMP press release and monthly report
- Summary of opinion: for positive and negative opinions
- European Public Assessment Report (EPAR):
  - ✓ Scientific discussion
  - ✓ Summary of product characteristics
  - ✓ Package leaflet
  - ✓ Labelling

Which information is already available?

Variations:

- Summary of opinion: for major variations affecting indications and contra-indications
- EPAR update including Product Information

Safety Issue:

- Press release
- Public statement
- Questions and Answers document

What's new? The EPAR

- ***The EPAR will also include:***
  - Risk management plan / pharmacovigilance plan
  - Specific obligations / main follow-up measures (conditional approval – exceptional circumstances)
  - Divergent opinions
  - Reference to compassionate use
- ***The abstract is replaced by the EPAR summary in language understandable by the Public***

Provision of information

As a result of the implementation of the new legislation, more information will be published:

- Assessment Report of applications withdrawn prior to the CHMP opinion
- Assessment Report for refusal of marketing authorisation
- More patient-friendly information on safety issues

→ In all cases: Questions and Answers for the public

Provision of information

Quality Review of Documents

- Templates
- Terminology

} In all EU languages

- Review of product information at the end of the evaluation (Summary of Product Characteristics and Package Leaflet)
- Guideline on summary of product characteristics

European Public database on medicines

Legal basis: Articles 57.1 (P) and 57.2 of Regulation (EC) No. 726/2004 of the European Parliament and the Council:

- Accessible to the general public
- Updated and managed independently of pharmaceutical companies
- Facilitates search for information on already authorised medicines
- Worded in an appropriate and comprehensible language (in all EU languages)

European Public database on medicines

It will contain all medicines approved in Europe with:

- Product Information (SPC, PL and labelling)
- Information on treatment of children
- Information on clinical trials

It should become the prescribing tool for European Physicians and the reference website on medicines for Patients and Consumers

9

European Public database on medicines

Technically:

- Accessible via a web portal
- In all the official languages of the EU
- Different levels of user access
- Connected to the other Eudra Systems (EudraVigilance, Eudra CT, etc)

10

European Public database on medicines

Development in stages:

- Priority given to products centrally authorised
- Subsequently be extended to any product within the Community

11

European Public database on medicines

Status of the project:

- Construction phase
- First pilot phase with limited data available to Member States
- 2006: first release to the general public

12

London, 28 March 2006
Doc. Ref. EMEA/112980/2006

EMEA WORKSHOP WITH HEALTH-CARE PROFESSIONALS

Establishing an interaction between the EMEA and Health-Care Professionals Organisations

Identification of the Health-Care Professionals' needs and expectations from the EMEA

Lisette Tiddens-Engwirda
Secretary General of the Standing Committee of European Doctors (CPME)

Health Professionals' needs and expectations from the EMEA

EMEA Workshop with Health-Care Professionals
London, 28 March 2006

The View of the Physicians

Lisette Tiddens-Engwirda
CPME Secretary General

www.cpme.be

Health Professionals' needs and expectations from the EMEA

CPME

Comité
Permanent des
Médecins
Européens

Standing
Committee of
European Doctors

www.cpme.be

CPME

- The Standing Committee of European Doctors - **CPME** - is the umbrella organisation representing approximately **2 million European doctors**

www.cpme.be

Membership

- Most representative non-governmental national medical organisations in EU/EEA countries (28 National Medical Associations/Chambers)
- 9 Associated Organisations
  - Independent European Medical Associations

www.cpme.be

Objectives of CPME

- to promote the **highest standards of medical training** and **medical practice**
  ➔ to achieve the **highest quality of health care** for the people of Europe
- to **promote public health, the relationship between patients and doctors and the free movement of doctors/patients within the European Union**

www.cpme.be

Patient safety: a CPME priority

- **Professional/Patients' mobility**
- **Quality of healthcare**
- **Informed/empowered patient**
- **Partnership doctor-patient**

www.cpme.be

Pharmaceuticals: legislation

- **EMEA Management Board: one representative of the doctors' organisations**
- **Information to patients: a left-over of the « Pharma review »/ G10**

www.cpme.be

Pharmaceuticals: G10 follow-up

- **EC Pharma Forum (DG SANCO and ENTR), 3WGs:**
  - **Information to patients**
  - **Pricing**
  - **Relative effectiveness**

www.cpme.be

Information and Telematics (1)

- EU Health Portal (EC DG SANCO)
- E-Health (EC DG INFSO):
  - Ministerial Conference (Malaga 2006)
  - World of Health IT Conference
  - Stakeholders group (e-Health Action Plan)
- European Public database on medicines

www.cpme.be

Information and Telematics (2)

- Eurobarometer 58.0 (March 2003)
  - Health professionals, the major source of information (45,3%); TV (19,8%) and Internet (3,5%)
  - Trust in the information:
    * Medical/Health organisations (84,4%)
    * Consumers organisations (67,2%)

www.cpme.be

Access to high quality information →

- Validated by a team of experts
- Easy to understand by non experts (literacy)
- User-friendly tools: telematics, leaflets, phone-lines?
- Information on all diseases (extra EMEA competences)

www.cpme.be

→ Patient safety (1)

- Partnership patient/doctor (peer to peer): diagnosis, treatment, informed consent
- Informed/empowered patient
- Pharmacovigilance: reporting adverse reactions to medicines → EMEA network

www.cpme.be

→ Patient safety (2)

- A team effort: all actors involved
- Luxembourg Declaration & follow-up stakeholders paper
- European Health Policy Forum (WG Patient Safety, Health information paper)

www.cpme.be

Conclusion: health professional needs and expectations

High quality, validated and reliable information on all medicines

→ EMEA: One-step European information source

www.cpme.be

Thank you

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www.cpme.be

London, 28 March 2006
Doc. Ref. EMEA/112985/2006

EMEA WORKSHOP WITH HEALTH-CARE PROFESSIONALS

Establishing an interaction between the EMEA and Health-Care Professionals Organisations

How to reinforce/initiate communication with Health-Care Professionals' representatives

Aage Schult
Executive Director of the European Society for Medical Oncology (ESMO)

How to Reinforce/Initiate Communication With Health-Care Professionals' Representatives

EMEA Workshop, 28 March 2006

European Society for Medical Oncology

- 4500 members in >100 countries
- Multidisciplinary oncologic focus, centered around MO
- Close Society cooperation/reciprocity with
  - ASCO
  - JSMO
  - CSCO
  - SLACOM
  - MOGA
- Collaboration with patients & patient advocacy
- Activities for/in the developing world
  - Annals of Oncology fee
  - Membership fee
  - CEE TF
  - DCTF
- Consultation to EMEA 2002-05: Orphan drugs & development of cancer (drs. Hansen, Schrijvers, Kosmidis, Casali, Schmoll)

Facts/needs/controversies in Oncology

- Increase in new cases by 50 % annually, 11 mill. today and 16 mill. in 2020 (WHO)
- By 2020: 3 of 5 new cases in developing world (WHO)
- Significant differences by country in survivals, also within Europe (EUROCARE)
- Access to treatment & care differ
- Focus from drugs to diseases, from cancer to patients?
- Fast track drug approvals versus safety and post-surveillance
- Methodology & clinical trials: Changing concepts?
- Patient organizations: Seminars, bill of rights, & registration of drugs
- Rare diseases: 50 % in cancer

EMEA – new aspects?

- Going from passive, one-way information to proactive/interactive dialogue
- Inviting input, not only from a "network of >3.500 European experts", but also from teaching societies
- Shortening the registration process, asking for advice, commitment, and co-responsibility of teaching societies?
- Evaluating drugs, but also need to consider expensive diagnostic tests

So, establishing interaction, - sharing responsibility, between EMEA and ESMO (or indeed any teaching society)?

- Consultation by ESMO experts on specific issues
- Value of specific oncologic drugs via dialogue with ESMO Faculty
- Also dialogue regarding orphan drugs/rare diseases, value of screening and prevention, plus methodological aspects
- Social aspects, quality of life, and drug availability
- Mutual press releases, policy development, and treatment guidelines
- Editorials and articles in Annals of Oncology
- Access to inform the medical/oncologic community about drug registrations or reasons for rejections
- A mutual EMEA/ESMO faculty
- Newsletter announcements, EMEA and ESMO

How to reinforce/initiate communication with Health-Care Professionals' representatives

So, establishing interaction, - sharing responsibility, between EMEA and ESMO (or indeed any teaching society)?

- Build a special mutual Task Force
- Website cooperation
- Participation in congresses and conferences
- Annual status meetings
- Develop a CME-based information channel
- Discussion of centralized procedures for oncologic drug registration in cooperation with FDA/EMEA/ASCO/ESMO

London, 28 March 2006
Doc. Ref. EMEA/113003/2006

EMEA WORKSHOP WITH HEALTH-CARE PROFESSIONALS

Establishing an interaction between the EMEA and Health-Care Professionals Organisations

Where and how can Health-Care Professionals further contribute to EMEA activities

K M Fox
President Elect of the European Society of Cardiology (ESC)

EUROPEAN SOCIETY OF CARDIOLOGY®

ESC Mission:

To improve the quality of life of the European population by reducing the impact of cardiovascular disease

Prof Kim Fox, President-Elect European Society of Cardiology

Constituents / Membership

- 49 National Cardiology Societies
- 23 Working Groups
- 2 Councils
- 4 Associations

~ 45,000 members

Prof Kim Fox, President-Elect European Society of Cardiology

36 Countries-650 Centres-52,000 Patients

Prof Kim Fox, President-Elect European Society of Cardiology

ESC – EMEA / CHMP Relations

Prof Kim Fox, President-Elect European Society of Cardiology

ESC-EMEA / CHMP Relations

1. Provide consolidated comments on EMEA / CHMP guidelines

- Dec 2003: Note for guidance on clinical investigation of medicinal products for the treatment of **cardiac failure**
- Dec 2003: Note for guidance on clinical investigation of medicinal products in the treatment of **lipid disorders**
- September 2005: Guideline on the clinical investigation of anti-anginal medicinal products in **stable angina pectoris**

Prof Kim Fox, President-Elect European Society of Cardiology

ESC-EMEA / CHMP Relations

2. ESC scientific workshops with regulatory input

- Acute Heart Failure - July 2003
- Combination therapy - June 2004
- Metabolic syndrome and Biomarkers - June 2005
  NB: Executive summary published in European Heart Journal
- Imaging biomarkers, drug eluting stents and gender effects planned for 2006

Prof Kim Fox, President-Elect European Society of Cardiology

ESC-EMEA / CHMP Relations

3. Regulatory symposium sessions at the ESC annual congress

- Vienna 2003: "Choice of endpoints in acute coronary syndromes: a scientific and regulatory challenge"
- Munich 2004: "Is combination therapy a strategy to reduce cardiovascular disease by over 80%?"
- Stockholm 2005: 'Developing medications for the heart risk continuum'

Prof Kim Fox, President-Elect European Society of Cardiology

ESC-EMEA Relations

4. EMEA roadmap to 2010

- ESC attended EMEA workshop on June 4th, 2004
- ESC sent letter to EMEA (June 2005) offering:
  - Ad-hoc scientific and medical experts for review and registration processes of pre- and post- authorization of medicines for human use
  - To further collaborate with EMEA on review of relevant CVD guidelines
  - To further collaborate with the EMEA in the development of its congress program
  - To provide information on the practice of cardiology, and the use of different therapy throughout Europe based on the European Heart Survey (EHS)

Prof Kim Fox, President-Elect European Society of Cardiology

ESC – EMEA Relations

ESC has access to several groups of specialists from:

- National societies
- Associations/Councils/WG
- Expert committees e.g. Guidelines, Euroheart Survey

ESC has access to Euroheart Survey network

Prof Kim Fox, President-Elect European Society of Cardiology

ESC – EMEA Relations

- Collaboration in guidelines preparation
- Contribute to the SPC
- Contribute to the EMEA expert committees
- Feedback to the EMEA on various matters where EMEA would request help from clinical experts
- Collaboration in preparation/implementation of risk management plan
- Contribution to pharmacovigilance (data collection, communication and audit)

Prof Kim Fox, President-Elect European Society of Cardiology