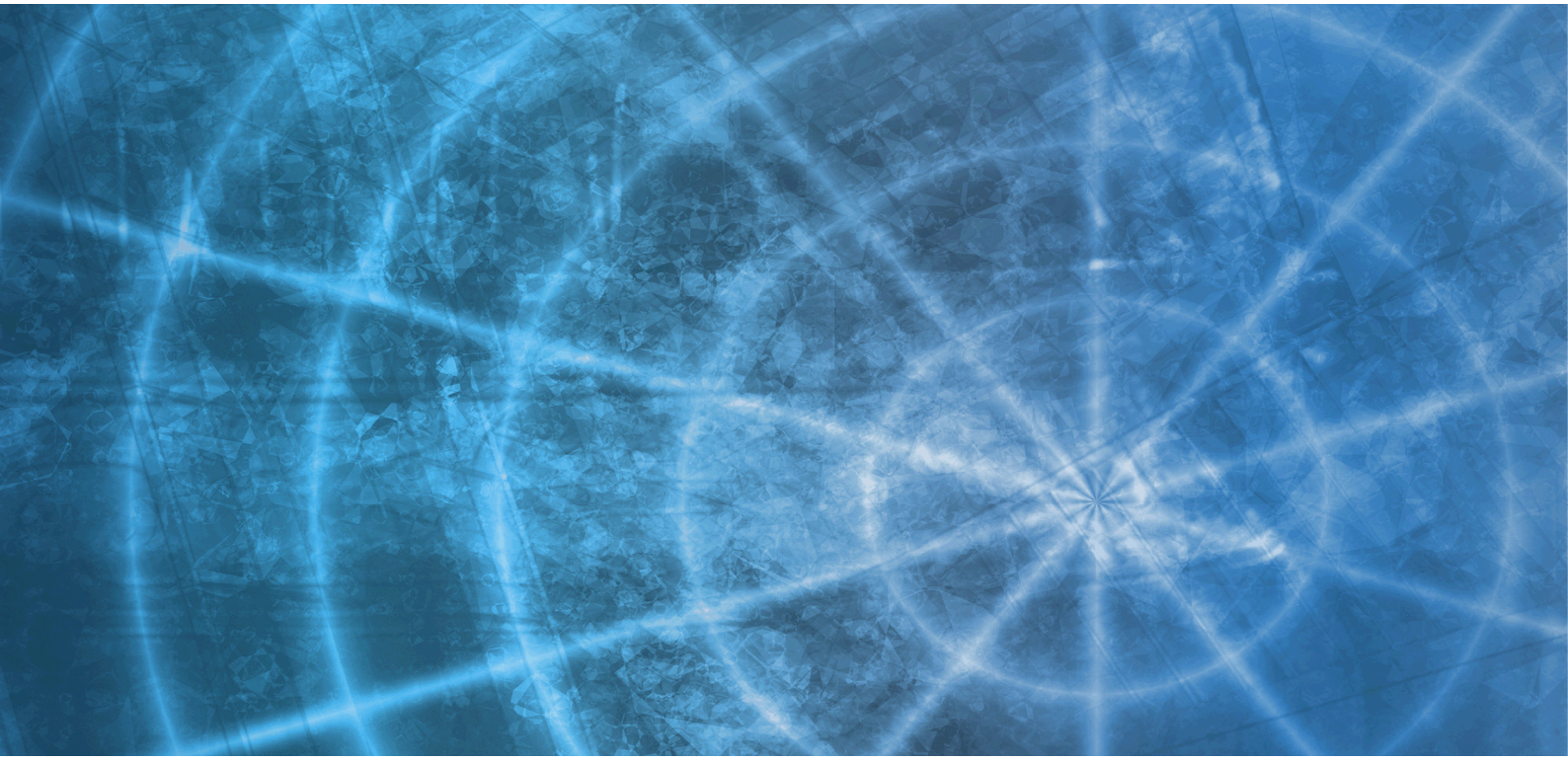
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

03 September 2010
EMA/232441/2010
Patient Health Protection



International workshop

Agenda

Draft reflection paper on ethical and GCP aspects of clinical trials of medicinal products for human use conducted in third countries and submitted in marketing-authorisation applications to the EMA

6-7 September 2010
European Medicines Agency, London, UK

Programme overview

Scope

The scope of this European Medicines Agency (EMA) workshop is to discuss and provide feedback on the 'Draft reflection paper on ethical and GCP aspects of clinical trials of medicinal products for human use conducted in third countries and submitted in marketing-authorisation applications to the EMA'.

Session topics

Introduction, welcome and overview of the draft reflection paper.

Session 1	International cooperation and regulatory authorities' perspective on the draft reflection paper.
Session 2	Clarify the practical application of ethical standards for clinical trials in the context of EMA activities.
Session 3	Determine the practical steps to be undertaken during the provision of guidance and advice in the drug-development phase.
Session 4	Determine the practical steps to be undertaken during the marketing-authorisation phase.
Session 5	International organisations' perspective on the draft reflection paper and their plans for the future.
Session 6	International cooperation on the regulation of clinical trials; review, inspection and capacity-building in this area.
Session 7	Clinical-trial participants; recommendations.
Session 8	Potential solutions and recommendations for the future.

Participants

Attendance at the meeting will be by invitation only, due to limitation of space. The meeting organisers are working to ensure the participation of a wide range of stakeholders' associations, patients' representatives, ethics committees, national competent authorities, commercial and non-commercial sponsors' associations, CROs and researchers.

Programme details

Day one – 6 September 2010 – Starts at 09.30

08.30 – 09.30 **Registration**

09.30 – 10.00 **Introduction**

- Welcome address and objectives of the workshop
  Speaker: Noël Wathion, European Medicines Agency
- Introduction to the Reflection Paper
  Speaker: Fergus Sweeney, European Medicines Agency

10.00 – 11.00 **Session 1 – International cooperation and regulatory authorities' perspective on the draft reflection paper**

Session chair: Patrick Le Courtois, European Medicines Agency
Session co-chair(s): Delese Darko, Food and Drug Board, Ghana

Key topics:

- International cooperation
- Regulatory authorities' perspective on the draft reflection paper

1.1 Candice Hilder, Health Canada, Canada
1.2 Li Jinju, SFDA, China
1.3 Evgeny Rogov, Federal Service on Surveillance in Healthcare and Social Development (Roszdravnadzor), Russia
1.4 David Lepay, Food and Drug Administration (FDA), USA

Discussion: 30 min.

11.00 – 11.20 **Coffee break**

11.20 – 12.20 **Session 2 – Clarify the practical application of ethical standards for clinical trials in the context of EMA activities**

Session chair: Nikos Dedes, PCWP co-chair (Patients' and Consumers' Working Party), EATG (European AIDS Treatment Group), Belgium
Session co-chair: Annagrazia Altavilla, PDCO Member - EEM (Espace Éthique Méditerranéen) - MED-HEM France

Key topics:

- Choice of comparator – placebo/active comparator
- Access to treatment post trial
- Clinical trials in vulnerable populations
- Ethics committee review

Regulatory authorities' perspectives

2.1 Harald Enzmann, CHMP member, BfArM, Germany

Sponsor representatives (commercial)

2.2 Peter Walton, EFPIA (European Federation of Pharmaceutical Industries and Associations), GlaxoSmithKline, UK

Sponsor representatives (non-commercial)

2.3 Raffaella Ravinetto, Institute for Tropical Medicine, Belgium

Ethics committee perspective

2.4 Cristina Torres, FERCAP Forum (for Ethical Review Committees in Asia and the Western Pacific), Philippines

2.5 Ock-Joo Kim, The Korean Association of Institutional Review Boards (KAIRB), Korea

12.20 – 13.20 **Lunch**

13.20 – 15.00 **Session 2 continues**

Patients' perspectives

2.6 Virginia Llera, GEISER Foundation (Group of Linking, Investigation and Support for Rare Diseases), Argentina

2.7 Perry Cohen, Parkinson Pipeline Project, USA

2.8 Hawa Dramé, Fondation Internationale TIerno et Mariam (FITIMA), Burkina Faso and Guinea

Discussion: 70 min.

15.00 – 16.20 **Session 3 – Determine the practical steps to be undertaken during the provision of guidance and advice in the drug-development phase**

Session chair: Patrick Salmon, CHMP member, Irish Medicines Board, Ireland

Session co-chair: Agnès Saint Raymond, European Medicines Agency

Key topics:

- Assessment of therapeutic needs in different regions and link to product development plan
- Scientific advice and guideline development
- Feasibility of clinical trials
- Measures to ensure good data quality when conducting trials; considerations for designing clinical trials

Regulatory authorities' perspectives

3.1 Clarice Petramale, National Health Surveillance Agency (ANVISA), Brazil

Sponsor's perspective

3.2 **Detlef Niese**, European Association for Bioindustries, Novartis, Switzerland

CRO's perspective

3.3 **Elizabeth Madichie**, ACRO, Pharmaceutical Product Development Inc.

European Forum for Good Clinical Practice (EFGCP) perspective

3.4 **Colin Wilsher**, EFGCP, Pfizer, UK

Discussion: 40 min.

16.20 – 16.40 **Coffee break**

16.40 – 18.00 **Session 4 – Determine the practical steps to be undertaken during the marketing-authorisation phase**

Session chair: Ian Hudson, CHMP member, MHRA, UK

Session co-chair: Gunnar Danielsson, GCP IWG member, MPA (Medical Products Agency), Sweden

Key topics:

- Information to be included in the dossier
- Assessment issues and process
- Inspection
- Transparency

Regulatory authorities' perspectives

4.1 **Pieter Neels**, CHMP member, Directoraat-generaal Geneesmiddelen Federaal Agentschap voor Geneesmiddelen en Gezondheids-producten - Agence Fédérale des Médicaments et des Produits de Santé, Belgium

4.2 **Laurent Brassart**, European Medicines Agency

Sponsor's perspective

4.3 **Torkil Fredborg**, European Federation of Pharmaceutical Industries and Associations (EFPIA), Lilly, UK

4.4 **Pavel Farkas**, European Generic Medicines Association (EGA) PLIVA Croatia, Ltd, R&D TEVA Generics System, Croatia

Discussion: 40 min.

Day two – 7 September 2010 – Starts at 09.00

09.00 – 10.40

Session 5 – International organisations' perspective on the draft reflection paper and their plans for the future

Session chair: Fergus Sweeney, European Medicines Agency
Session co-chair(s): Juhana E. Idänpään-Heikkilä, Council for International Organizations of Medical Sciences (CIOMS), Finland

5.1 Charles Mgone, European and Developing Countries Clinical Trials Partnership (EDCTP), The Netherlands
5.2 Gunilla Sjölin-Forsberg, Council for International Organizations of Medical Sciences (CIOMS), Switzerland
5.3 Laurence Lwoff, Council of Europe (COE), France
5.4 Otmar Kloiber, World Medical Association (WMA), France
5.5 Liliana Chocarro, World Health Organization

Discussion: 30 min.

10.40 – 10.50 **Coffee break**

10.50 – 12.40

Session 6 – International cooperation in the regulation of clinical trials; review, inspection and capacity-building in this area

Session chair: Emer Cooke, European Medicines Agency
Session co-chair: Pierre-Henri Bertoye, AFSSAPS, France

Key topics:

- Identification of opportunities and partners
- Action plan
- Resources
- Examples of initiatives

Regulatory authorities' perspectives

6.1 Ana Rodriguez, European Medicines Agency
6.2 Chao-Yi (Joyce) Wang, Food & Drug Administration, Chinese Taipei
6.3 David Lepay, Food and Drug Administration (FDA), USA
6.4 Aaron Sosola, Pharmacy, Medicines & Poisons Board, Malawi
6.5 Lucky Slamet, National Agency of Drug & Food Control, Indonesia
6.6 Umberto Filibeck, Italian Medicine Agency (AIFA), Italy

Developing Countries Vaccine Regulators' Network (DCVRN)

6.7 James Southern, DCVRN (South Africa)

Discussion: 50 min.

12.40 – 13.40 **Lunch**

13.45 – 15.15 **Session 7 – Clinical-trial participants; recommendations**

Session chair: Isabelle Moulon, European Medicines Agency
Session co-chair: [to be confirmed]

NGOs

7.1 Annelies Den Boer, WEMOS, The Netherlands
7.2 Irene Schipper, SOMO, The Netherlands
7.3 Antonio Ugalde/Nuria Homedes, Salud y Fármacos, USA and Argentina/Latin American Network of Ethics and Medicines (RELEM)

Patients' perspective

7.4 Amit SenGupta, Health Action International (Asia-Pacific), India
7.5 Kin-ping Tsang, Alliance for Patients' Mutual Help Organizations, APMHO, Hong Kong, China

Discussion: 40 min.

15.15 – 16.30 **Session 8 – Potential solutions and recommendations for the future. Conclusions and closing remarks**

Session chair: Harald Enzmann, CHMP member, BfArM, Germany
Session co-chair: Fergus Sweeney, European Medicines Agency

Key topics:

- Implementation within the current framework
- Solutions requiring changes to the legislation
- Final stakeholder views, with general discussion and conclusions

Summary of key points on the topic of the draft reflection paper

8.1 Maria Antonietta Antonelli, European Medicines Agency

Panel discussion:

Regulators

- **Alar Irs**, CHMP member, Estonia
- **Li Jinju**, SFDA, China
- **Clarice Petramale**, National Health Surveillance Agency (ANVISA), Brazil
- **David Lepay**, Food and Drug Administration (FDA), USA
- **Hayashi Yoshikazu**, Ministry of Health, Labour and Welfare, Japan
- **Evgeny Rogov**, Federal Service on Surveillance in Healthcare and Social Development (Roszdravnadzor), Russia

International organisations

- **Otmar Kloiber**, World Medical Association (WMA), France
- **Liliana Chocarro**, World Health Organization
- **Laurence Lwoff**, Council of Europe (COE), France

- **Gunilla Sjölin-Forsberg**, Council for International Organizations of Medical Sciences (CIOMS), Switzerland

Patients' representatives

- **Kin-ping Tsang**, Alliance for Patients' Mutual Help Organizations, APMHO, Hong Kong, China

Sponsors

- **Detlef Niese**, European Association for Bioindustries, Novartis, Switzerland

Ethics committee representatives

- **Cristina Torres**, FERCAP (Forum for Ethical Review Committees in Asia and the Western Pacific), Philippines

Conclusions and closing remarks:

- **Stefan Fuehring**, Pharmaceuticals Unit, DG Sanco, European Commission
- **Thomas Lönngren**, Executive Director, European Medicines Agency

16.30 **End of workshop**