EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

IPA Selected activities

Introductory meeting
1-2 February 2010

Presented by: Dr. Sylvie Bénéfice
Head of Meeting & Conference Management

An agency of the European Union

IPA Programme Methodology

Activities

- Participation of representatives in non-product related meetings as observers
- Provision of training
- Organisation of conferences in beneficiary countries for training purposes

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IPA Programme activities

Outline

- Participation in meetings and trainings – General conditions
  - Invited representatives
  - Reimbursement rules for meeting expenses
- Meetings
  - Human medicines meetings
  - Veterinary medicines meetings
  - Human & Veterinary medicines meetings
- Training
  - At the European Medicines Agency
  - External training courses
  - Focused training
- Conferences
- Conclusion – IPA team

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Participation in meetings and trainings General conditions

Invited Representatives

- 1 nominated representative per beneficiary country NCA as passive observer

  Active observer after closure of Chapter 1 on movements of goods

- Declaration of interest
- Confidentiality undertaking agreement

Participation in meetings and trainings General conditions

Reimbursement rules for meeting expenses in London

Travel

- Tickets from and to the place of origin in economy class
- Possibility of amending the return in some cases
- Partial reimbursement in case of round trip

Daily Allowance

- € 105 for meeting days

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Participation in meetings and trainings General conditions

Reimbursement rules for meeting expenses in London

Accommodation

- Hotel expenses up to £160 per night
- One night's accommodation prior to a meeting day, when airport departure is before 08.00 hours
- One night's accommodation after a meeting day, when airport arrival is after 23.00 hours

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Participation in meetings and trainings General conditions

Reimbursement rules for meeting expenses in London

Bookings

- Own arrangements
- Through MCM
  - To guarantee flights and hotel bookings at European Medicines Agency rates (25 hotel agreements)
  - To avoid expensive advance payments for meeting

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Participation in meetings and trainings General conditions

Reimbursement of expenses

- How: By bank transfer
- What: Daily allowance, travel, hotel
- To whom: NCA or individual experts
- THP Form to be filled in and bank statement to be provided

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Meetings
Human Medicines Meetings

Committee and Working parties meetings

HMPC (Committee on Herbal Medicinal Products)

Assisting the harmonisation of procedures and provisions concerning herbal medicinal products laid down in EU Member States

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Meetings - Human Medicines Meetings

Working group meetings

- Good Clinical Practice Inspectors Working Group
  Expert advice and support, on GCP inspection
- Ad Hoc Pharmacovigilance Inspectors Working Group
  Input and recommendations on PhV inspections in the context of post-authorisation processes EU Telematics
- GMP/GDP (Good Manufacturing Practice/Good Distribution Practice) Inspectors Working Group
  Guidance on GMP, work related to Mutual Recognition Agreements, new legislation impacts and harmonisation of GMP inspections

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Meetings - Human Medicines Meetings

Working group meetings (cont.')

- EMA/CHMP Working Group with Healthcare Professionals
  To set up a framework of interaction between the Agency, its Human Scientific Committees and Health Care Professionals
- Joint meeting between the EMA/Scientific Committees' WP with Patients' and Consumers' Org. and the EMA/CHMP Working Group with Healthcare Professionals
  Recommendations to the Agency and its human scientific committees on all matters of interest to patients in relation to medicinal products.

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Meetings - Human Medicines Meetings

Working group meetings (cont.')

- Name Review Group
  To evaluate whether the proposed invented name could create a public-health concern or potential safety risk
- EudraGMP database sub-working group
  Sub-working group (IT and GMP inspectors) in charge of the definition of the technical requirements for the EudraGMP project
- ENCePP Academic Centres Annual Meetings
  Scientific meetings to promote pan-EU partnerships to strengthen EU excellence in the field of PhV and Pharmacoepidemiology
- EudraCT TIG / Joint Operational Group and Paediatric subgroup

Meetings - Veterinary Medicines Meetings

Committee and Working parties meetings

- Immunological Working Party
  Recommendations to the Committee of Medicinal Products for Veterinary Use (CVMP) on all matters relating to immunological veterinary medicinal products (VMP)
- Efficacy Working Party
  Recommendations on efficacy and animal safety of VMP
- Safety Working Party
  Scientific expertise to the CVMP on the safety of VMP in the context of consumer and operator safety and on the establishment of maximum residue limits (MRLs)

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Meetings - Veterinary Medicines Meetings

Working group meetings

- Ad Hoc Pharmacovigilance Inspectors Working Group
  To promote an effective management of PhV inspections, to establish proficient communication and information exchange and to provide input into PhV legislation preparation
- GMP/GDP (Good Manufacturing Practice/Good Distribution Practice) Inspectors Working Group
  New and revised guidance on GMP, work related to Mutual Recognition Agreements, how new legislation impacts GMP inspection activity and harmonization of GMP inspections

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Joint Human & Veterinary Medicines Meetings

Working Party meeting

Quality Working Party

Joint CHMP/CVMP Quality Working Party providing recommendations to the Committees on the quality of human or veterinary medicinal products.

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Joint Human & Veterinary Medicines Meetings

Telematics Implementation Groups (TIG)

To reinforce exchange of information between stakeholders (general public, industry, Member States, European Commission and The Agency) to support pharmaceutical regulatory activities for both human and veterinary medicines.

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Joint Human & Veterinary Medicines Meetings

- EudraVigilance TIG
  Data processing network and management system for reporting and evaluating suspected adverse reactions during the development and following the marketing authorisation of medicinal products in the European Economic Area (EEA)
- EudraPharm TIG
  Source of information on all medicinal products for human or veterinary use that have been authorised in the EU and the EEA
- Eudranet TIG
  Eudranet II is a managed virtual private IP network based on encrypted tunnels over the public Internet

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Training – At the European Medicines Agency

Objectives

- European Medicines Agency Workshop for Small & Medium Enterprise's "Focus on Non-clinical Aspects"
- EU Good Clinical Practice Inspectors Working Group
- First Workshop on Advanced Therapy Medicinal products
- HMPC Assessors Workshop
- EU Pharmacovigilance Inspectors Working Group
- GCP Inspectors
- PhV Inspectors
- Quality Review of documents

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Training - External Training Courses

- DIA - Excellence in Pharmacovigilance: Clinical Trials and Post Marketing
- DIA - EudraVigilance Member States Training
- DIA - EudraVigilance Medicinal Products Dictionary
- European Medicines Agency Joint meeting with TOPRA

On demand workshop

- GMP in Ankara 21-22 October 2009

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Training - Focused Trainings

Training per predefined priority areas

- Acquis communautaire
- Pharmacovigilance
- Inspections
- Veterinary Medicines

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Conferences

- To exchange views and establish dialogue with interested parties
- To give an overview of the EU legislation on the regulation of medicinal products
- To provide feedback on experience of applying the *Acquis Communautaire* and related legal aspects
- To explain the role of guidelines
- To identify the differences between the EU and the existing legislation

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Conferences

- Period: September-December 2010 - 2011
- Location: beneficiary country
- Participants:
  - Project beneficiaries
  - NCA representatives
  - Stakeholders

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Conclusion

2009-2011

- Attendance of representatives to meetings and training held at the European Medicines Agency
- 3 conferences
- Identification of predefined priority areas training

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IPA team

Team Leader & Conference organiser	Young-Mi Lamine
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Finance/Budget	Svetlana Bari
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