EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 February 2013
EMA/35980/2013
Patient Health Protection

Medication-errors workshop

Final programme

28 February – 1 March 2013
European Medicines Agency, London, United Kingdom

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An agency of the European Union

Introduction

This two-day workshop is organised by the European Medicines Agency (EMA).

Medication errors with medicinal products are a major public-health burden and generally refer to mistakes in the processes of prescribing, dispensing, administering or monitoring medicinal products in clinical practice. In Europe, the medication-error rate in ambulatory care is estimated at 7.5% at prescription and 0.08% at the dispensing stage, whereas in the hospital setting the rates vary between 0.3–9.1% and 1.6–2.1% respectively[1]. At national level, various systems are in place to allow for medication-error detection, reporting and prevention, and the collaboration between organisations such as patient-safety institutions, pharmacovigilance centres and poison-control centres in one Member State can inform other Member States and inform work at European Union (EU) level.

Since July 2012, the EU pharmacovigilance legislation explicitly foresees reporting of suspected adverse reactions associated with medication errors and liaison with national patient-safety organisations to improve public health [Directive 2001/83/EC Articles 1(11), 101(1) and 107a(5)].

The aim of this workshop is to facilitate the implementation of these new legal provisions at EU level.

[1] 'Creation of a better medication safety culture in Europe: Building up safe medication practices', Council of Europe Expert Group on Safe Medication Practices (2006).

Welcome to all participants

Dear colleagues,

On behalf of the European Medicines Agency (EMA) and the Programme Committee I am pleased to welcome you to the EU regulatory workshop on medication errors.

Medication errors are the most common single preventable cause of adverse events in medication practice. Acknowledging medication errors as a major public-health burden, the new pharmacovigilance legislation explicitly foresees reporting of suspected adverse reactions associated with medication errors.

We are committed to working with all relevant stakeholders to bring about safer medication practices. This workshop is an excellent opportunity to bring together the available expertise with stakeholders from all areas of healthcare, including regulatory and public bodies, national patient-safety organisations, healthcare-professional and patient-consumer organisations, academia, learned societies and the pharmaceutical industry.

The workshop's objective is to develop and share best practices for the prevention of medication errors through raised awareness among the stakeholders involved in the reporting, evaluation and prevention of medication errors, and through greater clarity on what constitutes a medication error. A better understanding of how medication errors are managed at national level will enable the EU regulatory network to improve stakeholder cooperation at national and international level.

We believe that, within existing regulatory frameworks, a focused dialogue between regulators and stakeholders is crucial to set the scene for safer medication practice with a reduced public-health burden from medication errors.

We look forward to meeting you in London!

Yours sincerely

Guido Rasi

Executive Director

Programme overview

Scope

The workshop will be of interest to all stakeholders involved in the reporting, evaluation and prevention of medication errors: healthcare professionals; patient associations; regulators; national patient-safety organisations; pharmaceutical industry; regulatory professionals; academics; civil-society organisations; corporate decision-makers.

Sessions

Session 1 Medication errors in the product lifecycle and special populations.

Session 2 Reporting.

Session 3 Analysis of medication errors resulting in harm.

Session 4 Regulatory tools for managing the risk of medication errors.

Session 5 Implementation of preventive measures.

Session 6 The way forward.

Programme Committee

Peter Arlett	European Medicines Agency
Francesca Cerreta	European Medicines Agency
Emer Cooke	European Medicines Agency
Brian Edwards	International Society of Pharmacovigilance, United Kingdom
Henry Fitt	European Medicines Agency
Mick Foy	Medicines and Healthcare products Regulatory Agency, United Kingdom
Thomas Goedecke	European Medicines Agency
Dolores Montero	Spanish Agency of Medicines and Medical Devices, Spain
Isabelle Moulon	European Medicines Agency
Paolo Tomasi	European Medicines Agency

Programme details

Thursday, 28 February 2013

12.00 Registration

Go to reception on the ground floor to register and receive your badge. Then join delegates in room 2A.

13.00 Welcome and opening

Opening remarks

Guido Rasi

European Medicines Agency

Introduction and objectives of the workshop

Peter Arlett (conference chair)

European Medicines Agency

13.15 Keynote lecture

Public-health burden of medication errors and how this might be addressed through the EU pharmacovigilance system

David Cousins

The NHS Commissioning Board, United Kingdom

14.00 Session 1: Medication errors in the product lifecycle and special populations

Do we have a common understanding of medication errors?

Jeffrey Aronson (session co-chair)

University of Oxford, United Kingdom

14.20 Addressing medication errors during drug development, evaluation and in the post-authorisation phase

CHMP position paper on medication errors in the context of benefit/risk

Andrea Laslop (session co-chair)

Agency for Health & Food Safety, Austria

Evaluation, classification and weighting of medication errors from industry perspective

Elizabeth Swain

GlaxoSmithKline, United Kingdom

15.00 Medication errors in special populations or circumstances

Paediatric patients and their caregivers

Ian Wong

University of Hong Kong, China

Older patients and their caregivers
Denis O'Mahony
Cork University Hospital, Ireland

15.40 **Coffee break**

Session 2: Reporting

16.00 **Reporting medication errors at national level**

What should be reported and to whom
Mick Foy
Medicines and Healthcare products Regulatory Agency, United Kingdom

Experience from national patient-safety organisations
Mariá José Otero
Institute for Safe Medication Practices, Spain

16.40 **Encouraging reporting at healthcare professional and patient levels**

Guidance to patients and consumers on medication-error reporting
Kaisa Immonen-Charalambous (session co-chair)
European Patients' Forum, Belgium

Discussion of legal consequences for healthcare professionals
Carlos María Romeo-Casabona
University of Deusto and University of the Basque Country, Spain

17.20 **EudraVigilance reporting rules in the context of the EU pharmacovigilance system**

Operational definition of medication error for EU reporting requirements
Thomas Goedecke
European Medicines Agency

Good practice: MedDRA coding of case reports resulting in harm
Sabine Brosch (session co-chair)
European Medicines Agency

18.00 **End of day 1**

Friday, 1 March 2013

Session 3: Analysis of medication errors resulting in harm

09.00 **Spontaneous reporting: detecting medication errors and suitability of current systems**

Phil Tregunno
Medicines and Healthcare products Regulatory Agency, United Kingdom

09.30 **Identification of preventable ADRs from a regulatory perspective**

Almath Spooner (session co-chair)
Irish Medicines Board, Ireland

10.00 **Root cause analysis in context of WHO International Classification for Patient Safety**

David Cousins (session co-chair)
The NHS Commissioning Board, United Kingdom

10.30 **Coffee break**

Session 4: Regulatory tools for managing the risk of medication errors

10.50 **Routine risk minimisation; activities related to product information**

Product-naming issues
Annemarie Hellebek
Danish Society for Patient Safety, Denmark

Labelling and package leaflet
Jan MacDonald
Medicines and Healthcare products Regulatory Agency, United Kingdom

11.30 **Additional risk minimisation**

Healthcare professional and patient education
Tony West (session co-chair)
European Association of Hospital Pharmacists, Belgium

Development of prevention strategies for medicines and medical devices
Laurent Auclert
Sanofi-Aventis, France

12.10 **Regulatory tools for risk minimisation and their effectiveness**

Monitoring health outcomes and patient compliance
Sabine Straus (session co-chair)
Medicines Evaluation Board, The Netherlands

12.30 **Lunch break**

Session 5: Implementation of preventive measures

13.30 **Best-practice communication for healthcare professionals and patients**

Angeles Alonso
European Society of Cardiology, France

13.50 **European Commission's report on Patient Safety**

Agnieszka Daval-Cichon
European Commission

14.10 **Examples**

Regulatory perspective
Dolores Montero (session co-chair)
Spanish Agency of Medicines and Medical Devices, Spain

Medication errors: what patients can do to minimise them
François Houÿez (session co-chair)
European Organisation for Rare Diseases, France

14.50 **Medication Errors: an FDA perspective**

Carol Holquist
Food and Drug Administration, United States

15.00 **Coffee break**

Session 6: The way forward

15.20 **Panel discussion: collaboration between healthcare-provider organisations, patient-safety organisations, regulators and the pharmaceutical industry**

Angeles Alonso, European Society of Cardiology, France
Peter Arlett, European Medicines Agency, **(session co-chair)**
David Cousins, The NHS Commissioning Board, United Kingdom
Agnieszka Daval-Cichon, European Commission
Carol Holquist, Food and Drug Administration, United States
François Houÿez, European Organisation for Rare Diseases, France
Isabelle Moulon, European Medicines Agency, **(session co-chair)**
Michael Richardson, Bristol Myers Squibb, United Kingdom
Almath Spooner, Irish Medicines Board, Ireland

15.50 **Closing remarks and next steps**

Peter Arlett
European Medicines Agency

16.00 **End of conference**

List of speakers and panellists

Angeles Alonso	European Society of Cardiology, France
Peter Arlett	European Medicines Agency
Jeffrey Aronson	University of Oxford, United Kingdom
Laurent Auclert	Sanofi-Aventis, France
Sabine Brosch	European Medicines Agency
David Cousins	The NHS Commissioning Board, United Kingdom
Agnieszka Daval-Cichon	European Commission
Mick Foy	Medicines and Healthcare products Regulatory Agency, United Kingdom
Thomas Goedecke	European Medicines Agency
Annemarie Hellebek	Danish Society for Patient Safety, Denmark
Carol Holquist	Food and Drug Administration, United States
François Houÿez	European Organisation for Rare Diseases, France
Kaisa Immonen-Charalambous	European Patients' Forum, Belgium
Andrea Laslop	Agency for Health & Food Safety, Austria
Jan MacDonald	Medicines and Healthcare products Regulatory Agency, United Kingdom
Dolores Montero	Spanish Agency of Medicines and Medical Devices, Spain
Isabelle Moulon	European Medicines Agency
Denis O'Mahony	Cork University Hospital, Ireland
Mariá José Otero	Institute for Safe Medication Practices, Spain
Guido Rasi	European Medicines Agency
Michael Richardson	Bristol Myers Squibb, United Kingdom
Carlos María Romeo-Casabona	University of Deusto and University of the Basque Country, Spain
Almath Spooner	Irish Medicines Board, Ireland
Sabine Straus	Medicines Evaluation Board, The Netherlands
Elizabeth Swain	GlaxoSmithKline, United Kingdom
Phil Tregunno	Medicines and Healthcare products Regulatory Agency, United Kingdom
Tony West	European Association of Hospital Pharmacists, Belgium
Ian Wong	University of Hong Kong, China

Practical information

Venue

The European Medicines Agency can be reached:

- By Docklands Light Railway (DLR)
  The Agency is a short walk from either Westferry station or Canary Wharf station on the DLR. Services run from Bank, Tower Gateway, Lewisham, Stratford, King George V and Beckton.
- By Underground
  The nearest stop for Westferry Circus is Canary Wharf station on the Jubilee Line.
- By bus
  Canary Wharf is serviced by local bus numbers D3, D7, D8, 135 and 277.
- By boat
  River services run between Embankment, London Bridge and Canary Wharf throughout the day.
- From London City Airport
  Take a taxi to Westferry Circus or alternatively catch the Docklands Light Railway. which goes to Westferry station.

Map

Entering the building

The Agency operates a stringent security policy. Upon arrival at ground-floor reception, you will be given a security pass that will allow you to make your way to meeting room 2A on the 2nd floor. Tea and coffee will be available on your arrival in the 2nd-floor foyer.

Physical disability

Let us know if you would like any specific help or information that would make your stay more comfortable. We will be very happy to help.

Registration

We strongly advise you to arrive up to one hour before the start of the workshop (i.e. at 12:00), to allow you time for registration and settling down. The registration will take place on the 2nd floor.

Meeting room

This workshop will benefit from a full house. You will be able to sit wherever you wish; note that the only reserved seats are for the speakers, panellists and organisers of the workshop.

Presentations

We will not circulate paper printouts of speakers' PowerPoint presentations. However, you will be able to download the presentations from the Agency's website approximately two weeks after the end of the workshop.

Catering

The Agency has a restaurant and a deli bar that offer a variety of food and drinks during the day. They both operate a cashless payment system. No cash or credit/debit cards are accepted.

You will be able to purchase a visitor card at the registration desk. In addition, visitor card terminals are available in the 1st-floor reception area and 3rd-floor restaurant. The terminals accept both GBP and EUR. The terminals issue a card with the balance of cash received less a £3 deposit for the card (i.e. if £10 is put into the machine, you will receive a card with £7 that can be spent in the restaurant and deli bar. The £3 will be refunded when the card is returned.)

At the end of your visit, simply reinsert the card in one of the visitor card terminals and the deposit plus any account balance will be refunded. If visiting the Agency frequently, visitors may wish to retain the card for future use.

Please note that the machine refunds in GBP coins only. For this reason, we encourage you to retain the card for future use or not to load it with more than £20.

Laptop computers

For those of you travelling from the continent and wishing to use your laptop, may we remind you to bring with you an appropriate UK power adapter.

Media disclaimer

The Agency records or broadcasts a number of its meetings, including some virtual meetings. This is part of the Agency's commitment to the principle of transparency as enshrined in the Treaty on European Union. The Agency herewith informs attendees that this particular meeting will be recorded and broadcast.

By attending this meeting you consent to any recording or broadcast.

Conference venue and secretariat

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