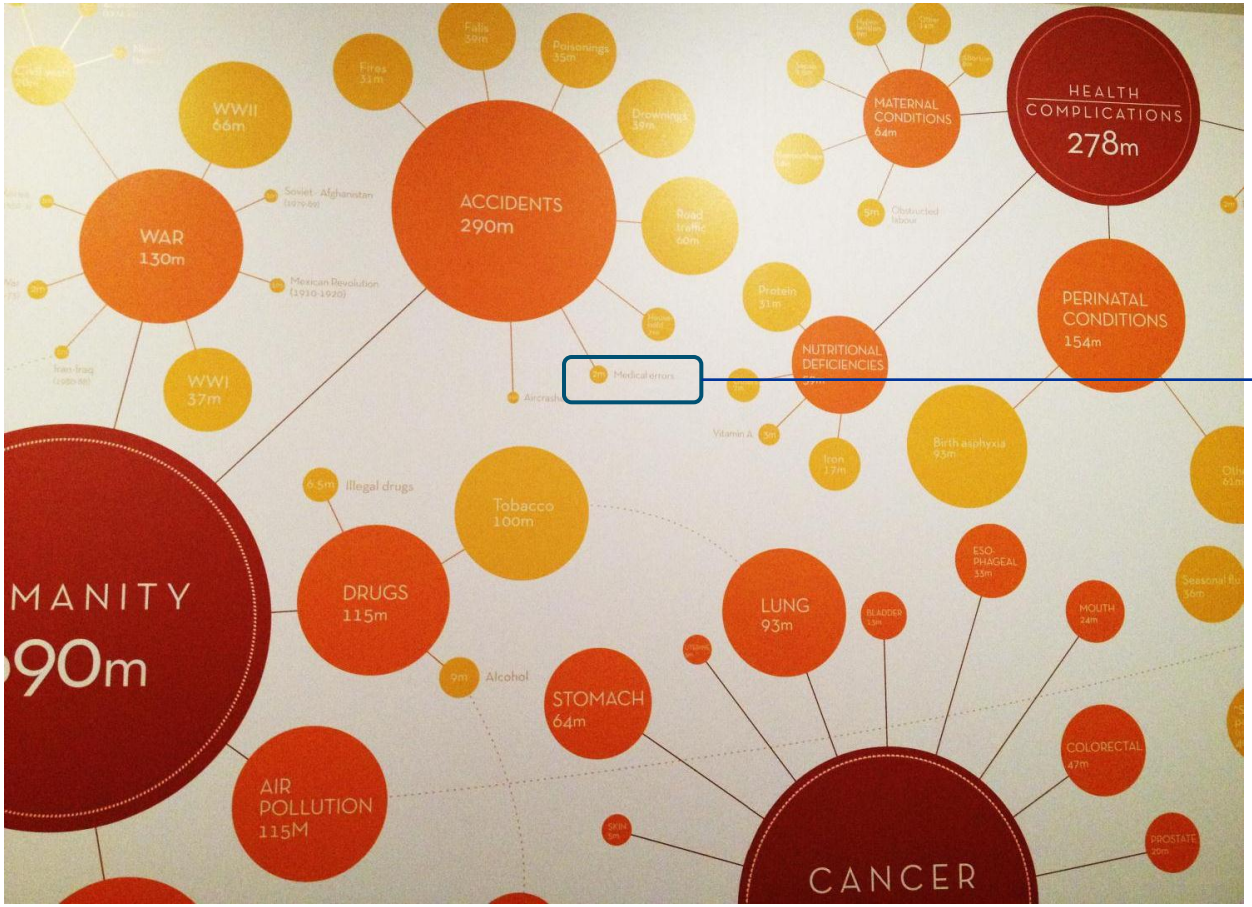
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EU Regulatory Workshop on Medication Errors

Patients/Consumers Working Party and Healthcare Professionals Working Group Joint Meeting, 27-28 February 2013

Presented by: Dr. Thomas Goedecke
Pharmacovigilance and Risk Mangement

What were the greatest causes of death in the 20th century?



Medication errors account for 2m deaths globally!

From David McCandless' graphic commissioned to accompany the exhibition '*Death – A Self Portrait*' at the Wellcome Collection London, November 2012.

The facts about medication errors

- Most common single preventable cause of adverse events in medication practice
- Major public-health burden with an estimated annual cost between 4.5 - 21.8 billion € (World Alliance for Patient Safety 2010)
- 18.7 - 56% of all adverse drug events among hospital patients result from medication errors that would be preventable[1]
- Medication-error rates in EU[1]:
  - Ambulatory care: 7.5% at prescription, 0.08% at dispensing
  - Hospital care: 0.3–9.1% at prescription, 1.6–2.1% at dispensing

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).

Regulatory background

- **New EU pharmacovigilance legislation** requires
  - Reporting of suspected adverse reactions associated with medication errors to EudraVigilance
  - Member States to liaise with National Patient Safety Organisations
- **WHO draft report** on reporting and learning systems for medication errors: detecting, analysing and preventing within Pharmacovigilance Centres (FP7 funded project 'Monitoring Medicines')*
- **CHMP draft position paper** on medication errors in context of benefit-risk balance
- **FDA draft guidance** for industry on safety considerations for product design to minimize medication errors*

*under public consultation

Position Paper on potential medication errors in the context of benefit risk balance and risk minimisation measures (EMA/274183/2012). Draft under consultation, CHMP (2012)
Safety Considerations for Product Design to Minimize Medication Errors. Draft guidance under consultation, FDA (2012)

Legal basis I

Directive 2010/84 (EC) Recital (5)

For the sake of clarity, the definition of the term 'adverse reaction' should be amended to ensure that it covers noxious and unintended effects resulting not only from the authorised use of a medicinal product at normal doses, but also from medication errors and uses outside the terms of the marketing authorisation, including the misuse and abuse of the medicinal product.

Directive 2010/84 (EC) Recital (17)

Member States should operate a pharmacovigilance system to collect information that is useful for the monitoring of medicinal products, including information on suspected adverse reactions arising from use of a medicinal product within the terms of the marketing authorisation as well as from use outside the terms of the marketing authorisation, including overdose, misuse, abuse and medication errors, and suspected adverse reactions associated with occupational exposure.

Legal basis II

Directive 2001/83/EC Article 1(11) - Definition

Adverse reaction: A response to a medicinal product which is noxious and unintended.

Directive 2001/83/EC Article 101(1)

Member States shall operate a pharmacovigilance system……to collect information on the risks of medicinal products as regards patients' or public health. That information shall in particular refer to adverse reactions in human beings, arising from use of the medicinal product within the terms of the marketing authorisation as well as from use outside the terms of the marketing authorisation….

Directive 2001/83/EC Article 107a (5)

Member States shall ensure that reports of suspected adverse reactions arising from an error associated with the use of a medicinal product that are brought to their attention are made available to the Eudravigilance database and to any authorities, bodies, organisations and/or institutions, responsible for patient safety within that Member State. They shall also ensure that the authorities responsible for medicinal products within that Member State are informed of any suspected adverse reactions brought to the attention of any other authority within that Member State. These reports shall be appropriately identified in the forms referred to in Article 25 of Regulation (EC) No 726/2004.

Good Pharmacovigilance Practices (GVP)

Module VI – Definition of an adverse reaction

An adverse reaction is a response to a medicinal product which is noxious and unintended [DIR Art 1]. This includes adverse reactions which arise from:

- the use of a medicinal product within the terms of the marketing authorisation;
- the use outside the terms of the marketing authorisation, including overdose, off-label use, misuse, abuse and medication errors;
- occupational exposure.

1st EU Regulatory Workshop

- 28th February – 1st March 2013, EMA premises, London
- Organised by the EU Regulatory Network and EMA
- More than 180 participants

Objectives of the workshop

- **Primary objective**: raise awareness amongst the stakeholders involved in the reporting, evaluation and prevention of medication errors to facilitate the implementation of the new legal provisions at EU level → safer medication practice
- **Secondary objectives**:
  - Common understanding of what constitutes a medication error and the new legal requirements for reporting cases of medication error at EU level
  - Better understanding of how medication errors are managed at national level
  - Sharing best practice for the prevention of medication errors
  - Proposals to facilitate stakeholder co-operation at national and international level

Stakeholders invited to participate

- Healthcare professional organisations (16)
- Patient consumer organisations (6)
- Regulatory bodies: EU National Regulatory Agencies, European Medicines Agency, other international regulatory bodies (34)
- Public health bodies: National Patient Safety Organisations, European Commission's Directorate General for Health & Consumers Working Group for Patient Safety and Quality of Care, WHO (18)
- Academia/learned societies (13)
- Pharmaceutical industry and their service providers (35)

Anticipated outputs of the workshop

- Meeting report & workshop presentations published on the EMA website
- Publication in a peer-review journal
- Concept paper for regulatory and scientific guidance on best practice for medication errors, including coding reports of medication error in EudraVigilance
- Development of a communication strategy to enhance exchange of information between national competent authorities, pharmacovigilance centres and patient safety organisations
- Strategy to streamline EU (regulatory) network resources

The Programme

- *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 (panel discussion)

Programme

How can you provide your input/feed-back?

The workshop is attended by representatives of the Patient/Consumer Working Party and of the Healthcare Professionals Working Group

- For questions to be addressed during the workshop or feed-back please contact your representatives

or

- Send us an email to medicationerrors2013@ema.europa.eu (by 28th February noon)

Further information

Please visit the EMA website www.ema.europa.eu

Home → News and Events → Calendar

Thank you for your attention.

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HCP Organisations participating

- UK Clinical Pharmacy Association
- Italian Association of Pharmaceutical Medicine
- European Union of General Practitioners
- European Association of Hospital Pharmacists
- Drug Commission of the German Medical Association
- Portuguese Association of Graduated in Pharmacy
- European Organisation of Rare Diseases (EURORDIS)
- European Society of Cardiology (ESC)
- Pharmaceutical Group of the European Union (PGEU)

Patient/Consumer Organisations participating

- AGE Platform Europe
- European Cancer Patient Coalition (ECPC)
- European Federation of Allergy and Airways Diseases Patients' Associations (EFA)
- European Patient's Forum
- European Public Health Alliance (EPHA)
- Global Alliance of Mental Illness Advocacy Networks Europe (GAMIAN)
- International Patient Organisation for Primary Immunodeficiencies (IPOPI)