Risk Communication on Medicines Moving Forward

SCOPE WP6 Workshop
Madrid 16-17 June 2016

June Raine  MHRA, UK
Risk Communication on Medicines WP6 Workshop

- Workshop WP6 in context of SCOPE Joint Action
- Reflection on what has been delivered by Work Package 6
- Challenges and opportunities
- Moving forward from SCOPE WP6 to strengthen risk communication
SCOPE Joint Action formal award decision adopted by European Commission – project officially started 18 November 2013

Maximum level & largest possible contribution from Commission of 70% funding

“Exceptional utility”
Strengthening public health protection

- Capabilities
- Collaboration
- Competence
- Communication
The SCOPE Joint Action

Share expertise and best practice
Deliver practical tools and guidance
Operate pharmacovigilance in Europe

By Member States
For Member States
With Member States
Public health importance

Studies in EU member states have estimated that 20% to 70% of adverse drug reactions preventable.

*Pirmohamed et al 2004 BMJ 329; 15-19*
*Rottenkolber 2011, Pharmacoepi & Drug Safety; 20: 626–634*

Success of risk minimisation needs to be evaluated.

If ineffective, alternative strategies need to be considered.
What did WP6 set out to achieve?

- Collect information on risk communication practices in the EU network
  - Understand communication channels and tools used, with frequency, strategy, and engagement approaches

- Explore knowledge, attitudes and preferences of NCAs, HCPs and patients towards different communication tools & channels in Member States
  - Determine effectiveness of different risk-communication methods
What has Work Package 6 achieved?

• **Two years’ worth of invaluable work**
  – A full understanding of EU risk communication practices

• **Practical deliverables**
  – Proposals for risk communication improvement toolkit
  – Guidance for web-based safety communication

• **Outcome of deliverables**
  – Direction and ideas for risk communication strategies in MS
  – Highlight good practice in EU network for web-based safety information
And by whom?

National communication methods audit – SE
Impact assessment of risk communication – IE
Good Practice – IT
Web-portals – UK

Partners:
DE  HR  NL  NO

Work package lead – Spain
Risk Communication Workshop
- bringing everyone together

National Competent Authorities
Healthcare Professionals
Patients and consumers organisations
World Health Organisation UMC
European Medicines Agency
Academia and scientific research
EUPATI, EAMI, Lareb
Current knowledge – science of risk communication

The changing nature of communication and regulation of risk in Europe

Ragnar Lofstedt, Frederic Bouder, Jamie Wardman and Sweta Chakraborty

Kings Centre for Risk Management, Kings College London, UK; Department of Technology and Society Studies, University of Maastricht, Maastricht, The Netherlands; School of Psychology, University of Lincoln, Lincoln, UK; Centre for Socio-Legal Studies, University of Oxford, Oxford, UK
1. Patients do not perceive all risks equally
2. Trust-building and two-way communication demands skills to respond to media scares
3. Proactive communication: the right message at the right time
4. Healthcare professionals are the crucial channel between regulators & patients. But it is challenging.
5. Country (++) and therapeutically (+) sensitive communications are critical

Frederic Bouder, WP6 Workshop
So where are we now?

- Audit of national methods – high response, high ambition to improve
- MS using multiple tools/channels to strengthen information uptake
- Some MS Integrating safety communications in prescribing and dispensing electronic tools
- Collaboration with opinion leaders and key scientists in relevant field enables understanding of needs

Annika Wennberg and Jane Ahlqvist Rastad, WP6 Workshop
NCA web-portals

- **User-testing** very important
  - Wide audience
  - Responsive to social media?

- **Consider format** of information - structure data
  - Use engaging information: videos, infographics
  - Central repository can provide everything in one place
  - Responsive web design
  - New channels e.g. social media and mobile apps

- **Search engine** is key

- **Quality control** steps – “official” agency guidelines
What we hear from risk communication “audiences”

- Trusted sender is NCA
- Patients want prompt information, HCPs after full investigation
- Targeting – more HCPs read if relevant to them
- RC Repetition helps
- Educational materials have low recognition
- Email and POC alerts as well as hard copy
What really helps too ….

Accessible risk management plans

François Houyéz

Academic detailing

Dr Roar Dyrkorn

Treatment with valproate for female patients: Checklist for patients and prescribers

A. Checklist for Prescribers

- Name of Patient /carer
- I confirm that the above-named patient does not respond adequately to or tolerate other treatments and requires valproate
- I have discussed with the above-named Patient/carers:
  - The overall risks of an approximately 10% chance of birth defects and up to 30-40% chance of a wide range of early developmental problems that can lead to significant learning difficulties in children exposed to treatment with valproate during pregnancy.
  - Individual risk can be minimised by use of the lowest possible effective dose
  - The need for contraception (if child-bearing age)
  - The need for regular review of the need for treatment
  - The need for urgent review if the patient is planning a pregnancy
  - I have given the patient/carers a copy of the patient information booklet
Figure 1: Active substances with and without additional RMAs per year of marketing authorisation.

- Without additional RMAs
- With additional RMAs

Year of marketing authorisation:

1995: 1
1996: 17
1997: 14
1998: 21
1999: 17
2000: 25
2001: 30
2002: 26
2003: 14
2004: 1
2005: 32
2006: 2
2007: 15
2008: 28
2009: 33
2010: 27
2011: 6
2012: 21

Introduction EU-RMP
Proposals for improvement

- Practical guidance on aspects of risk communication
- Adapt to local situation and context and resources of NCA
- Multidisciplinary teamwork
- Training including media handling
- Engage external experts if possible
- Two-way with HCPs, patients
- Dissemination via professional bodies/learned societies?
- Electronic mechanisms, POC alerts, social media, website linkages
- Journal articles, editorials

Amelia Cupelli & Ilaria Baldelli
DIMEA cycle for continuous improvement in risk communication

- Designing communication
- Implementing activities
- Monitoring
- Evaluating
- Adjusting if needed

Consultation with patients and HCPs
Challenges and opportunities

Seniors
b. 1920-1945

Baby Boomers
b. 1946-1965

Gen Xers
b. 1966-1979

Gen Yers
b. 1980-2000
Average 47% of respondents with limited HL across 8 countries

Health Literacy problem for general pop just for particular groups
New technology
Public hearings

Opportunity of public hearings to be introduced later in 2016
PRAC Strategy to measure impact

- Leverages ongoing work by regulators, academia and industry (effectiveness of risk minimisation)

- PRAC to develop criteria to measure impact of specific regulatory action eg after referrals
Insights from research

Benefit : harm

Theo Raynor, UK
EC Shortcomings Report

- Focus on improvement of the PIL rather than on the SmPC
- Guidelines should be revised
- Further strengthen the input from patients during development process
- Showcase best practice examples of leaflet design
- Explore the use of electronic media
- Consider those countries with more than one official language in the electronic media strategy
Moving forward from WP6

- Publish all work of WP6 including outputs of workshop

- NCAs to use the two outputs “Risk Communication – Proposals for Improvement” and guidance for web-portals as platform for progress
Moving forward from WP6

• More research is needed!
  – “there is no consensus on the best way to represent quantification of risk”
  – Formal testing of communication tools
  – Methodologies for evaluation of impact
  – Etc
• Inspired by SCOPE WP6 establish a multidisciplinary “network” to keep up momentum on improving risk communication in NCAs?
Our WP6 Vision

• Evidence-based use of world class risk communication practices and tools
• Maximising opportunities of new technology, mechanisms and media
• Working in partnership with patients, healthcare professionals and academia
• Delivering measurable public health benefit

Shaping the pharmacovigilance world of the future
SUCCESS IS A JOURNEY, NOT A DESTINATION
Muchas Gracias AEMPS!
Felicitations!