



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Take Home Messages

PCWP & HCPWP Workshop on Risk Minimisation Measures
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Chair, Pharmacovigilance Risk Assessment Committee

An agency of the European Union



Key points:

- Goal is maintaining a positive benefit risk balance as evidence is gathered in clinical use reducing uncertainties which exist at time of authorisation
- Use the current regulatory tools optimally
- Risk is part of life - get the balance of RMMs right – more is not necessarily better – unintended consequences
- Involve patients and HCPs from start of developing RMMs
- Capture real-life experiences from patients and Healthcare Professionals and use these in optimising RMMs
- Patient organisations have a key role in addressing the issue of health literacy

Key points:

- Measuring the effectiveness of RMMs is now embedded in the product life-cycle – much more to learn about optimal use of this tool and how to act on results
- Much can be learnt from case studies - each safety issue is scenario specific and needs evaluation in the therapeutic context
- Importance of involving healthcare professionals in evaluating the scientific evidence underpinning selection of RMMs and supporting uptake into clinical practice
- Huge potential of maximising utility of patient registries to monitor effectiveness of risk minimisation measures

Key points:

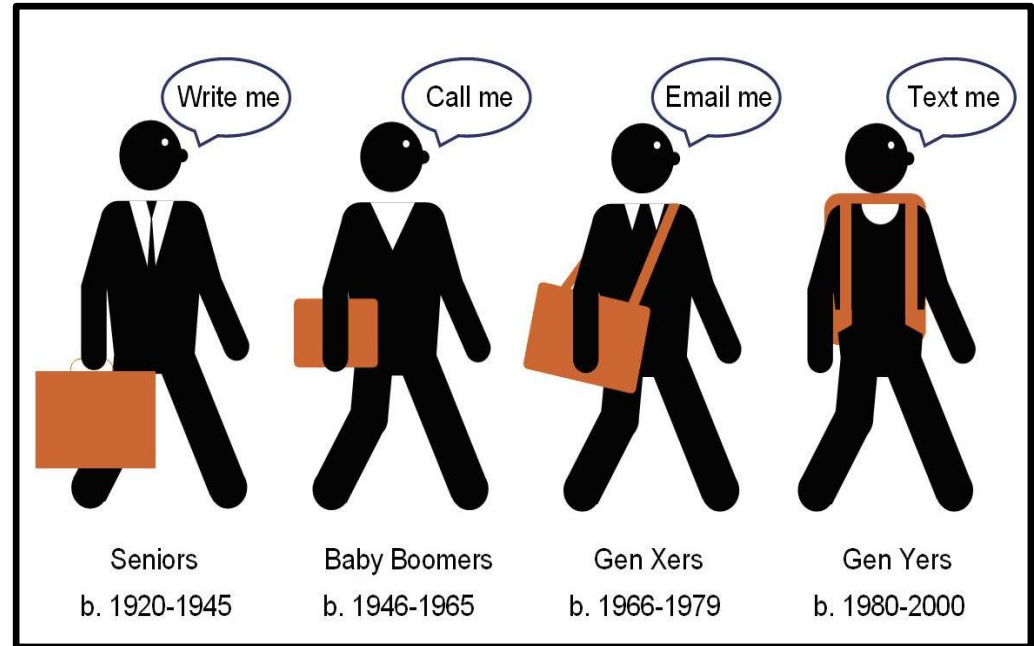
- Communication of RMM messages is facilitated by trust - trust is a vital facilitator of a learning organisation
- Type of trust which exists within one relationship has knock-on effects for trust relations elsewhere in the chain
- Regulators need to find ways of influencing different links and stakeholders
- How to create an atmosphere of risk awareness without undermining trust – cultivate active “critical trust”?

Designing the future needs to start now

Research needed to inform the way forward

All involved actors need to play as a team - active collaboration at every level

HCPWP Topic Group on RMMs will take today's outcome forward in work plan





Thank you

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