Implementation of Risk Minimisation Measures in Clinical Practice: Challenges and Opportunities

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Presentation Overview

EMA Workshop on RMMs Sept ‘15

Actions Following the Workshop

Challenges

Opportunities

Conclusions

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Why do we need RMMs?

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MEMO/08/782

Brussels, 10 December November 2008

Strengthening pharmacovigilance to reduce adverse effects of medicines

Medicinal products contribute considerably to the health of EU citizens. They can, however, also have adverse effects. It is estimated that 5% of all hospital admissions are due to an adverse drug reaction (ADR), and that ADR is the fifth most common cause of hospital death. In light of experience and following an assessment made of the EU pharmacovigilance system (supervision and monitoring of ADR) made by the Commission it has become clear that new measures are necessary to improve how the EU rules operate on the

http://europa.eu/rapid/press-release_MEMO-08-782_en.htm?locale=en

Remember this memo?

- It is estimated that 5% of all hospital admissions are due to an adverse drug reaction (ADR)
- ADRs are the fifth most common cause of death in hospital
- An estimated 197,000 deaths per year in the EU are caused by ADRs
- The total cost to society of ADRs in the EU is €79bn

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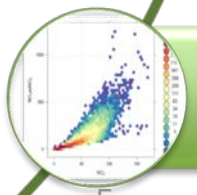
Conclusions: EMA's Workshop on RMMs

Optimise use of current regulatory tools

Collaboration with HCPs & patients is key to developing RMMs

Understand factors that affect adherence to RMMs by patients & HCPs

Effective communication



A more systematic approach to measuring the effectiveness of RMMs at different levels

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2015/08/event_detail_001193.jsp&mid=WC0b01ac058004d5c3

Actions Following the Workshop

RMM Topic Group: Objectives

- Discuss current practices/experience in development/implementation of RMMs
- Brainstorm how to facilitate input from HCPs on feasibility, info & evaluation of RMMs; product-specific issues, therapeutic class and overall therapeutic environment
- Discuss how to better inform HCPs on ongoing activities/initiatives in the EU regulatory network for post-authorisations and prepare recommendations as appropriate.

Challenges - Questions

Optimisation of existing RMMs and development of new RMMs

Balance & proportionality

Feasibility

Unintended consequences of an RMM

Medication Errors

- Tresiba® (insulin degludec)
- Ionsys® (fentanyl)

Challenges – Answers (1)

If a medication is available in multiple strengths, there is always a risk?

Packaging needs to be clearly designed for all users (e.g. colour blind / visually impaired insulin users) and to prompt HCPs in counselling

Space on packaging for pharmacy labels?

Delay between launch of RMM and regular use of medication

DHCPs - Lost in the post? Surgery? Ward? Pharmacy?

Challenges – Answers (2)

Vague checklists – not diagnosis / condition specific

Set number of “information materials” per pack used for multiple patients

Information overload (checklists, cards, communications from all areas)

Health system hierarchy & reporting

Not all HCPs have access to diagnoses / indications

Opportunities - Questions

Learnings from those with real-life experience implementing RMMs, e.g. nurses, pharmacists

New tools allow instant access to online information

Ensuring correct media & correct tool used for each situation

Message adapted to each audience

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Opportunities – Answers (1)

Involve HCPs earlier on in the development process

Guides should cover all HCPs involved in medication use

Target communications with appropriate tool and to appropriate audience, using mixed media

Use of scientific publications / communications / events

Opportunities - Answers (2)

Integration into Institutional protocols / guidelines

Incorporate into education of HCPs (CE/CPD*)

Point of prescribing / dispensing software alerts

Access to shared eHealth records (with indications / diagnoses)

Multi-professional collaboration & shared responsibilities

*Continuing Education / Continuous Professional Development

Some Practical Solutions

GP-Pharmacist Pharmacotherapy Meetings (e.g. “PTAMs” in NL)

GP Quality Circles (e.g. NL, DE)

Practice Guidance / CPD / CE (e.g. UK)

Dossier Pharmaceutique Partagé (e.g. FR, BE)

Good Pharmacy Practices (pharmacovigilance e.g. ES)

Error process database (e.g. “Patientsikkerhed”, DK)

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Conclusions – Closing the Loop

- Engage earlier with HCPs, and after launch
- Broaden and tailor RMMs & communications with the right tool
- ➢ Should we be using CE/CPD more for RMM implementation, use, uptake & adherence?

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Ask

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