How can healthcare professionals contribute to generate data on behavioural changes?

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Background


Scope of this presentation
Share some of the learnings from the TG and implications for regulators and HCPs
### Conclusions from the Sept 2015 EMA Workshop on RMMs

<table>
<thead>
<tr>
<th>Optimise use of current regulatory tools</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collaboration with HCPs &amp; patients is key to developing RMMs</td>
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<tr>
<td>Understand factors that affect adherence to RMMs by patients &amp; HCPs</td>
</tr>
<tr>
<td>Effective communication</td>
</tr>
<tr>
<td>A more systematic approach to measuring the effectiveness of RMMs at different levels</td>
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</tbody>
</table>
Collaboration with HCPs & patients

Pts & HCPs should be involved early in design:
- both to optimise existing and develop new RMMs
- as much can be learnt from those with real-life experience of implementation of RMMs, e.g. nurses, pharmacists.

Engagement:
- can take place through the existing frameworks of EMA’s working parties
- as well as through new interactions with other organisations and individuals.

HCP WP RMM “Topic Group” (TG)
- Created along side several other thematic TGs end of 2015
- Objectives
  - Discuss current practices/experience in development/implementation of RMMs
  - Brainstorm how to facilitate input from HCPs into the feasibility, information and 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.
- Survey of HCP WP on 4 recent RMMs
- Analysis & recommendations ready
- Next steps....
Understand factors that affect adherence to RMMs

To avoid unnecessary burden, regulators need to ensure that risk minimisation measures are:
- Well balanced
- Feasible

Consideration should also be given to unintended consequences of a measure:
- E.g. lack of safer alternatives when restricting access to a critical medicine

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- Survey of HCP WP on 4 recent RMMs
- Analysis currently underway
- Next steps....
Understand factors that affect adherence to RMMs

A strong network and communication channels that allow healthcare professionals to engage with patients and regulators needs to be in place.

Regulators need to engage further with stakeholders and more is to be done to create an atmosphere of risk awareness without undermining trust.

HCP WP RMM “Topic Group” (TG)
(As previously described)

Impact of Pharmacovigilance
PRAC Strategy
This Workshop

PRAC strategy has identified four key areas of focus:

1. Effectiveness of risk minimisation actions
2. Effectiveness of specific pharmacovigilance processes
3. Enablers of effective pharmacovigilance including stakeholder trust and engagement
4. Method identification and development
Overview of Survey

HCPs (primary & secondary care, specialist & generalist) completed questionnaire over summer 2016

Implementation and adherence to RMMs in practice – what works well and what are the barriers?

Tailored (for each RMM), structured, closed questionnaire with open space for comments to elaborate / give practice experience

Valproate, high strength insulin, bisphosphonates/denosumab & fentanyl patches
Challenges - Questions

- Optimisation of existing RMMs and development of new RMMs
- Balance & proportionality
- Feasibility
- Unintended consequences of an RMM
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.

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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

- 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
Opportunities - Answers

- 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

- 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 Practice-based Solutions
(from professional organisations)

- Professional Audit in Practice (various)
- GP-Pharmacist Pharmacotherapy Meetings (e.g. “PTAMs” in NL)
- Good Pharmacy Practices (pharmacovigilance e.g. ES)
- GP & Pharmacist Quality Circles (e.g. NL, DE, PT, CH)
- Research Ready Pharmacies (e.g. UK)
- Real World Evidence (e.g. PT)
- eHealth: Dossier Pharmaceutique Partagé (e.g. FR, BE)
- Error process database (e.g. “Patientsikkerhed” DK)

Communication from EU-Level Organisations?
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