

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

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Background

EMA's Healthcare Professionals' Working Party
(HCP WP) Topic Group on Risk Minimisation
Measures (RMM TG), Oct 2015 - Present

Scope of this presentation

Share some of the learnings from the TG and
implications for regulators and HCPs

Creation of the RMM TG

Conclusions from the Sept 2015 EMA 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

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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 - 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 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](#)²

This [Workshop](#)³

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

Challenges - Answers

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

**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**

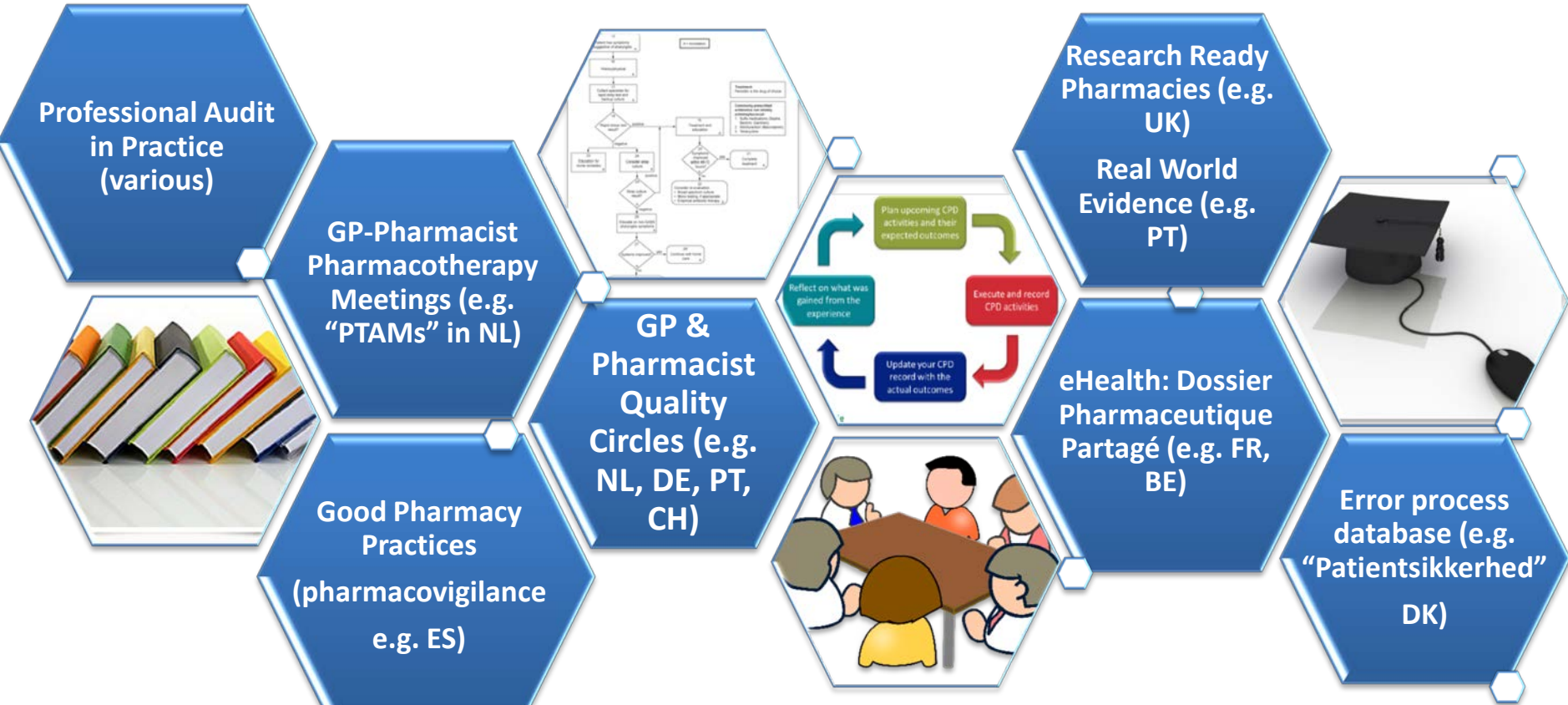
**Access to shared
eHealth records
(with indications /
diagnoses)**

**Multi-professional
collaboration &
shared
responsibilities**

*Continuing Education / Continuous Professional Development

Some Practice-based Solutions

(from professional organisations)



Communication from EU-Level Organisations?

References

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