Update on the follow up actions from the Risk Minimisation Measures Workshop in 2015

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Introduction

EMA's workshop on RMMs (Sept 2015)

Report[1] available on the EMA website

Scope of this presentation

Share the learnings from the workshop

Describe what has been done since

Conclusions from the Workshop

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

A note on the presentation format

Findings on the left

Actions / recommendations on the right

1. Optimise use of current regulatory tools

SmPC and PIL should be:

- optimised

- adapted to needs of audience

- better describe benefits and risks.

Patient organisations:

- have a key role in addressing the issue of varying health literacy.

EMA workshop with PC/HCP WP representatives: Communication on medicines – March 2016

Increase use of tools:

- including the PL

- graphics and effects tables will be explored in a context of participatory design.

Provide better targeted information to segments of the public and patient communities.

Patients, HCPs and their representative organisations have a central role to play in the communication process.

2. 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 currently underway
- Next steps….

3. 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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3. 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]

- Workshop[3]: measuring the impact of pharmacovigilance activities 5-6th Dec 2016

The 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

4. Effective communication

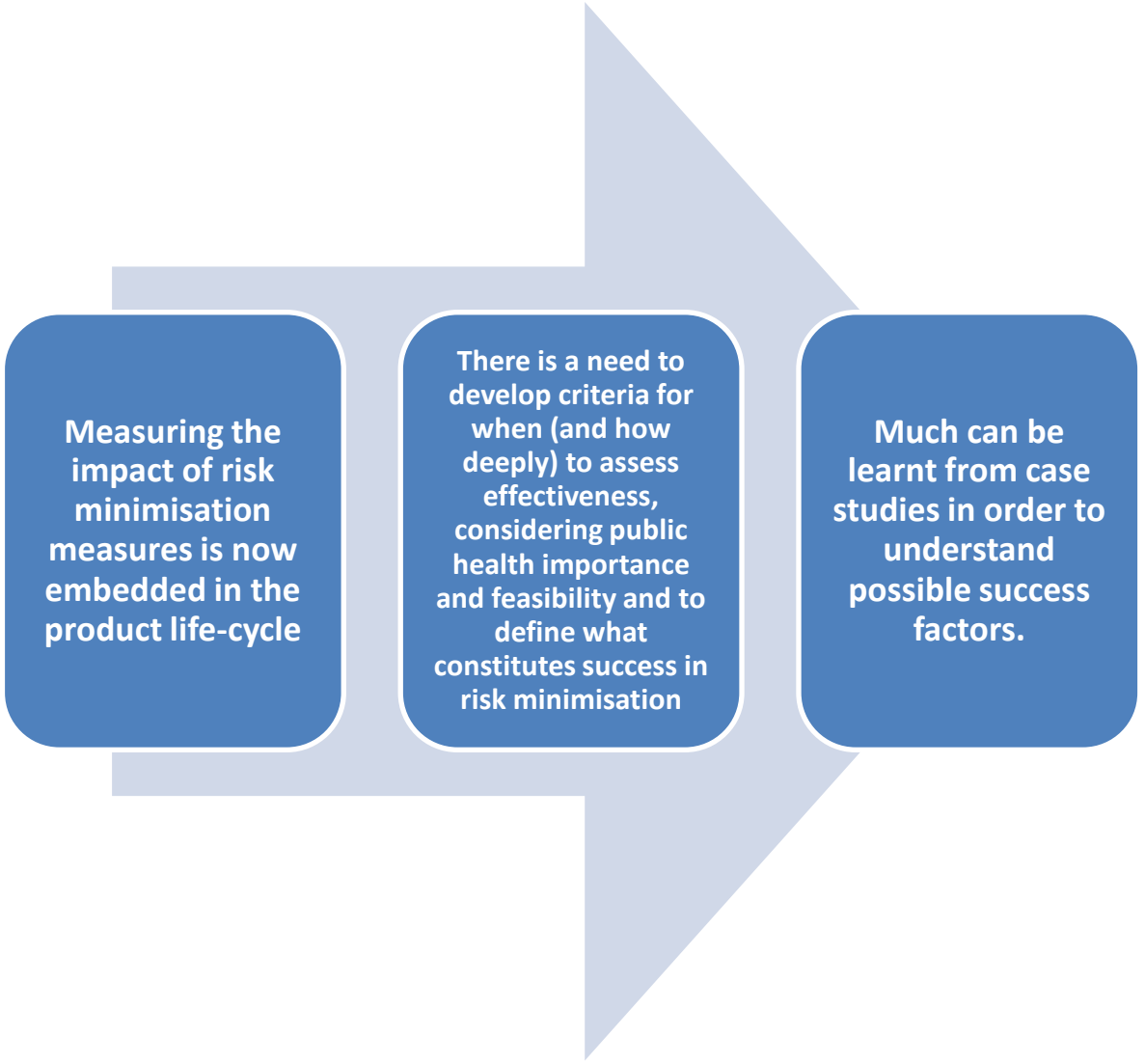
Need to maximise existing communication tools and exploring new technologies

New tools allow instant access to online information

Need to move beyond paper-based communications, e.g. web-based or social media, ensure correct tool is used for each situation, message is adapted to each audience.

- EMA HCPWP/PCWP dissemination practices
- HCPWP/PCWP topic group on social media
- EMA workshop[4] with PC/HCP WP reps on social media – 19th Sept 2016
- IMI-WEB-RADR workshop[5] - 19th Oct 2016

5. Systematic approach measuring effectiveness of RMMs



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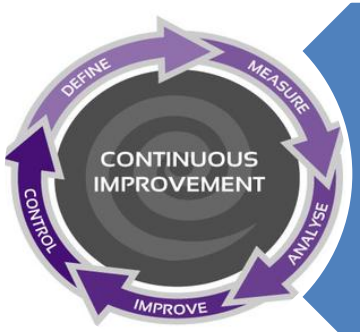

Engaging patients', consumers' and healthcare professionals' associations on the impact of RM will help guide process improvements.

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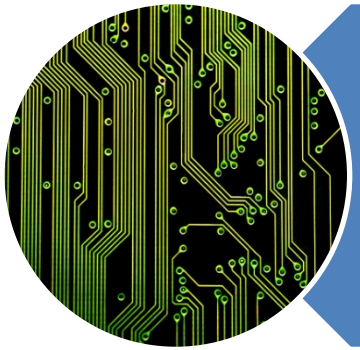
Impact of Pharmacovigilance

(As previously described)



Finally, there is a huge potential for maximising patient registries to detect risks and to monitor effectiveness of RMMs.

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Patient Registries[6] task force

Set-up in 2014 with strategy to:

1. Identify and evaluate existing data sources including national databases, electronic health records and existing patient registries
2. Determine if the need for data is best addressed through a registry
3. Investigate with registry coodinators the possibility to amend or extend an existing registry if needed
4. Defining the core components of a new registry as applicable

Some Practice-based Solutions

(from professional organisations)

- Good Pharmacy Practices (on pharmacovigilance, e.g. ES[7])
- GP Quality Circles[8] (e.g. NL, DE)
- GP-Pharmacist Pharmacotherapy Meetings[9] (e.g. "PTAMs"[10] in NL)
- Dossier Pharmaceutique Partagé (e.g. FR[11], BE[12])
- Practice Guidance[13] / CPD[14] / CE (e.g. UK)

➢ Communication from EU-Level Organisations?

References

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

[2]http://www.ema.europa.eu/docs/en_GB/document_library/Other/2016/01/WC500199756.pdf

[3] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2016/04/WC500204177.pdf

[4] http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2016/07/event_detail_001311.jsp&mid=WC0b01ac058004d5c3

[5] http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2016/08/event_detail_001316.jsp&mid=WC0b01ac058004d5c3

[6]http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000658.jsp&mid=WC0b01ac0580961211

[7]http://www.portalfarma.com/Profesionales/consejoinforma/Paginas/Buenas-practicas-Farmacia-Comunitaria.aspx

[8]https://www.researchgate.net/publication/278716124_Pharmacotherapeutic_Circles

[9]https://www.medicijngebruik.nl/english/products-and-services

[10]http://aop.sagepub.com/content/40/9/1640.abstract

[11]http://www.ordre.pharmacien.fr/Le-Dossier-Pharmaceutique/Qu-est-ce-que-le-DP

[12]http://www.apb.be/fr/corp/Le-pharmacien/role-et-taches-principales/Pages/Dossier-pharmaceutique-partage.aspx

[13]https://www.gov.uk/government/publications/toolkit-on-the-risks-of-valproate-medicines-in-female-patients

[14]https://www.gov.uk/government/publications/e-learning-modules-medicines-and-medical-devices/e-learning-modules-medicines-and-medical-devices