EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

How can we listen to stakeholders and the public? – A regulatory perspective

MESH Virtual Workshop:

Trusting, Collaborating and Listening - Engaging Public and Communities with Vaccine Studies

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Declarations

The views expressed in this presentation are the personal views of the presenter and the authors of the referenced article and may not be understood or quoted as being made on behalf of or reflecting the position of the European Medicines Agency or one of its committees or working parties.

The presenter and the authors of the study presented have no conflict of interests to declare.

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Regulators' mechanisms to listen to stakeholders and the public

- Written consultations
- Stakeholder forums and meetings
- Working parties with patient and healthcare professional representatives
- Patient and healthcare professional members in management board and committees
- Public hearings
- Risk minimization measures effectiveness studies
- Media monitoring

Usual media monitoring at a regulatory body

Daily with **reference to the organisation**:

- New medicines
- Safety concerns with medicines
- Policies and regulatory requirements
- Stakeholder interactions
- Political news relating to science, health, medicines, the organisation

July – November 2015

at EMA's Pharmacovigilance Risk Assessment Committee (PRAC)

EU review procedure for HPV vaccines and complex regional pain syndrome (CRPS) / postural orthostatic tachycardiasyndrome (POTS) reported to the authorities as suspected adverse reactions

Does medicinal product-specific media monitoring
have the potential to
enhance communication in terms of
proactivity and preparedness
for information provision
to the public
by a regulatory body?

Study during the review procedure:

"Application of real-time global media monitoring and 'derived questions' for enhancing communication by regulatory bodies

the case of human papillomavirus vaccines"

[Bahri P, Fogd J, Morales D, Kurz X (2017)]

Note: It is not the objective of this presentation or the referenced article to provide information on the safety profile of HPV vaccines or to explain the outcome of the EU referral procedure on HPV vaccines and CRPS/POTS, as these are presented elsewhere.

Media monitoring of
global online news on HPV vaccines
prospectively in real-time every day Sep-Dec 2015
using the Vuelio® tool

4230 selected news items
personal stories, scientific
and regulatory topics

Inductive media content analysis

- Interpreted the explicit and implicit content, connotations and underlying assumptions
- Identified explicit and implicit questions, including those raised due to lack of specific knowledge or anticipated once more information would be provided in the public domain, information needs and expectations of the public (incl. sub-populations)
- Formulated them as ‘derived questions’ in abstract manner and scientific-regulatory language and concepts
- Categorised 50 derived questions in 12 themes

Examples for derived questions

3.3. What is the likely magnitude of underreporting, and has a sensitivity analysis been performed for the observed/expected analysis to take underreporting into account?

8.1. What safeguards are there to ensure that marketing authorisation holders do not manipulate data they submit to the authorities?

Derived questions theme categories

1 Assessment scope

2 Case data

3 Frequency

4 Other data

5 Causal association

6 Overall safety

7 Aluminium

8 Data trustworthiness

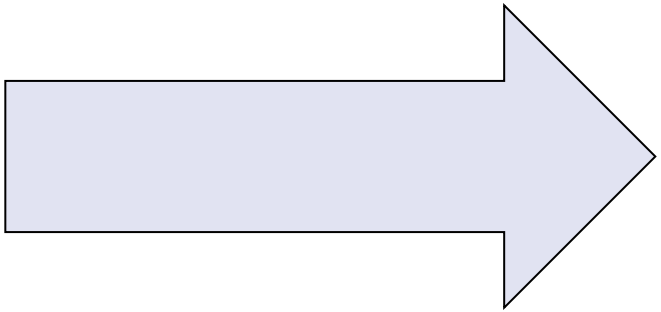
9 Standards and integrity

10 Benefit

11 Benefit-risk balance

12 Further steps and research

Media content analysis
- Weekly
- Cumulatively (derived questions)



EMA's Pharmacovigilance Risk Assessment Committee (PRAC)

EMA's Media Office

Utility of medicinal product-specific media monitoring

(1) Confirmed that public concerns regarding CRPS and POTS would be covered by the ongoing EU review or previous assessments

(2) Meet specific information needs proactively in the public statement on the EU review outcomes

(3) Altered the tone of the public statement with respectful acknowledgement of the health status of patients with CRSP or POTS

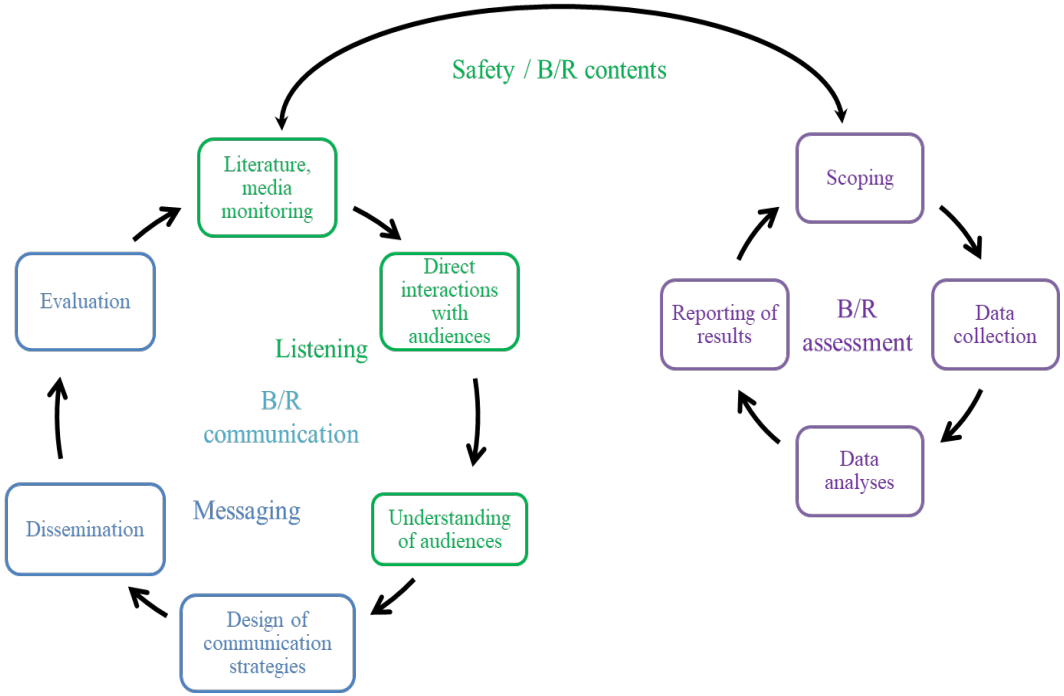
(4) Predicted all queries from journalists at media briefing and after

(5) Able to respond immediately to queries and be well prepared for observing parliamentary hearings by means of talking points

Conclusions

- Prospective real-time media monitoring could form part of regular surveillance for medicines of high public interest
- Development of efficient monitoring strategies is recommended
- Translation of media content in scientific-regulatory concepts and language with familiar question format and neutral framing fits regulatory thought process and focusses on fulfilling public information needs

⇨ Empowering and facilitating dialogue between regulators and the public



[ADVANCE (2017). Developing communication strategies on vaccine benefits and risks]

Need for a continuous feedback loop

Need for multidisciplinary approaches for planning and evaluating communication events

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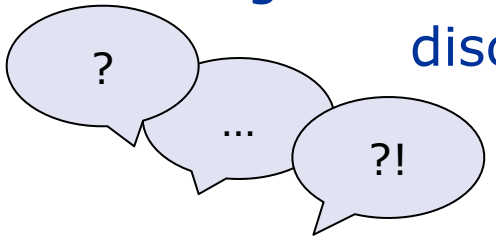
Thank you for your attention.

And now: The COVID pandemic - Looking forward to our discussion



Further information

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