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nº 49

Can news content analysis support preparing for communication?

A real-life media listening experience with HPV vaccines at the European Medicines Agency (EMA)

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Communicating about benefit-risk assessments of medicines is a major part of the activities of a regulatory body. When vaccines are concerned, communication preparations should be done with specific attention to the regular debates on vaccines in the public domain. In Europe, doubts about safety are the main driver for vaccine hesitancy of individuals for whom vaccines are provided, or their parents.[1] Therefore, the need for vaccine safety communication systems and processes capable of effective stakeholder interactions, preparations and conduct of communication by regulatory bodies, taking into account specific information needs of the public and sub-populations, has been advised for at European Union (EU)[2] and global level.[3]

Media monitoring for the purpose of listening to the public has been amongst the long-standing recommendations for communication about medicines in general[4] as well as medicine-related safety concerns and risk mitigation in particular.[5] However, the utility of media monitoring for regulatory bodies and whether resource allocation could be justified have been unclear.

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When the European Medicines Agency (EMA), in July 2015, started an EU procedure assessing HPV vaccines with regard to the potential causality of complex regional pain syndrome (CRPS) and postural orthostatic tachycardia syndrome (POTS) reported to the authorities as suspected adverse reactions, the EMA decided to conduct a study with the objective to evaluate the utility of media monitoring in real life.

Prospective daily monitoring of worldwide online news on websites of e.g. online newspapers, news outlets, television stations and consumer organisations was performed. From September to December 2015, 4230 news clips, or posts, were identified (Figure 1), containing personal stories, scientific and policy/process-related topics.

Through an inductive content analysis, explicit and implicit concerns voiced in these posts were identified and formulated as 'derived questions'. These derived questions were worded in regulatory-scientific language and abstract manner, i.e. formulated differently from the questions raised

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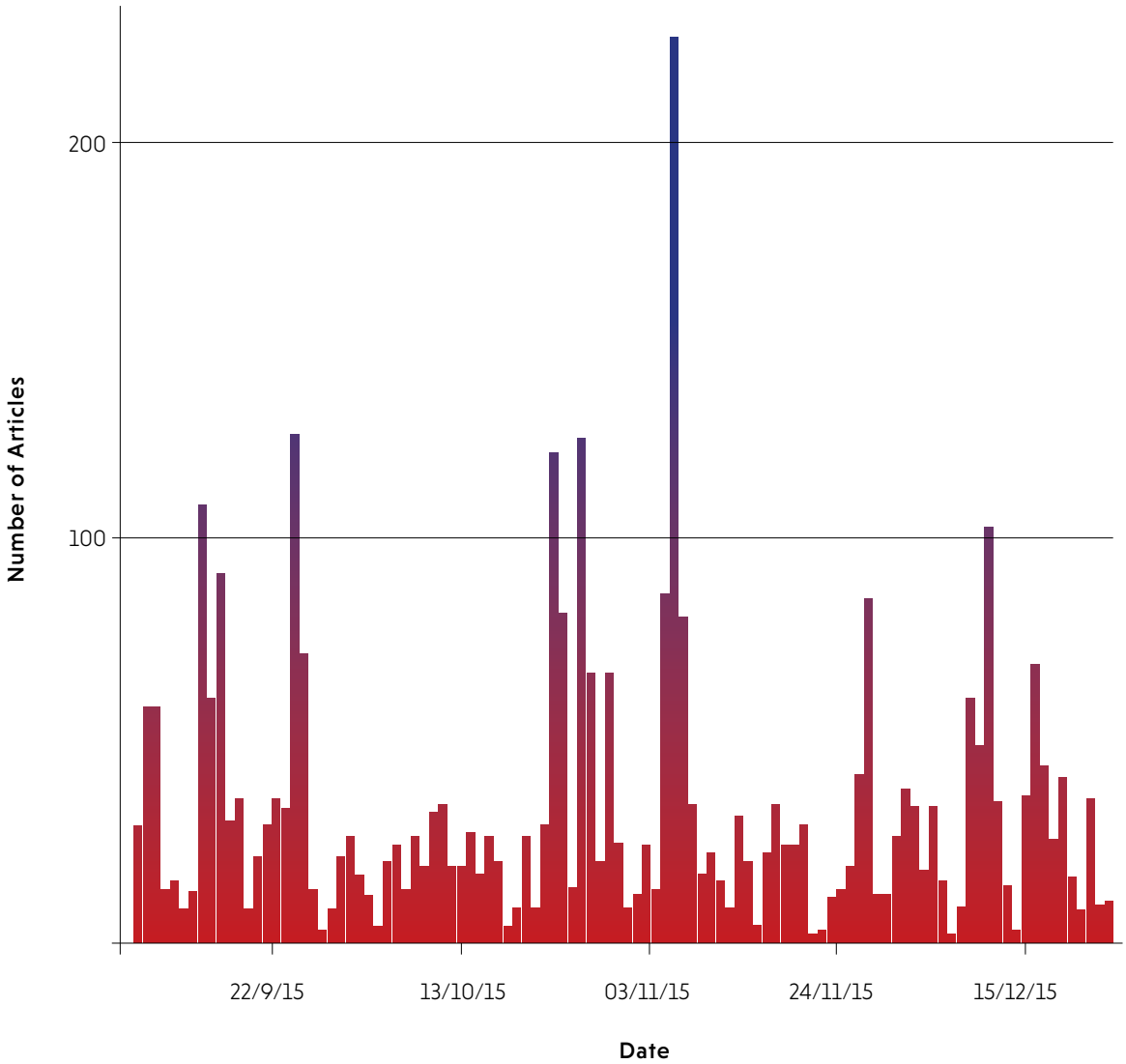
Quote this article as:

P Bahri (2018). Can news content analysis support preparing for communication? **www.HPVWorld.com**, *49*

Figure 1

HPV vaccines news by day



Time chart depicting volume of media coverage worldwide from 7 September to 23 December 2015 by day (generated by the Cision® system).[6]

Media monitoring can support regulatory bodies in (1) their scoping of risk assessments (2) their communication proactivity and (3) their preparedness for prompt responses to journalists

explicitly in the media or formulated anew if the concern had not been presented in the media as a question at all, but the discussion implied a question or knowledge gap which was considered, as part of the media content analysis, as important to fill. This included questions that were anticipated to be raised once more information would be available for publication. Medical, methodological as well as integrity-related aspects were discussed in the media. 50 derived questions were generated and categorised into 12 themes, which are presented with the 12 high-level questions in Table 1. Based on the media content from September to 22 October 2015, considerations (weekly) and the 50 questions (two weeks prior to the scheduled assessment outcome) were provided to the colleagues involved in the risk assessment or in the communication planning.

The evaluation was performed through three approaches, and the results showed utility as detailed in Table 2. It was demonstrated that media monitoring can support regulatory bodies in (1) their scoping of risk assessments to ensure public concerns are addressed in the assessments; (2) their communication proactivity through enriching public statements with scientific details and committed, empathic tone; and (3) their preparedness for prompt responses to journalists and at public meetings. Derived questions in scientific-regulatory language seem to be a familiar format and effective, as they make the media debates readily understandable in the regulatory environment and motivate addressing the identified concerns. It is suggested that listening to the public through media monitoring could form part of regular safety surveillance for medicines of high public[6] interest. ■

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Table 1

Categories of themes with high-level derived questions based on a content analysis of the worldwide media coverage for HPV vaccines from 7 September to 22 October 2015[6]

Theme 1 - Assessment scope:
Derived high-level question 1.0.: What is the scope of the assessment conducted for the EU referral procedure for HPV vaccines?

Theme 2 - CRPS and POTS case data:
Derived high-level question 2.0.: What kind of case reports of CRPS and POTS in association with HPV vaccines have been reviewed by the competent authorities, and how?

Theme 3 - Frequency assessment:
Derived high-level question 3.0.: What are the reporting rates and actual frequencies of CRPS and POTS in association with HPV vaccines?

Theme 4 - Other (i.e. not case) CRPS and POTS data:
Derived high-level question 4.0.: What kind of data has been reviewed for the EU referral procedure for HPV vaccines in addition to individual case reports?

Theme 5 - Assessment of causal association:
Derived high-level question 5.0.: How has the assessment of CRPS and POTS in causal association with HPV vaccines been performed?

Theme 6 - Overall safety and other safety concerns:
Derived high-level question 6.0.: What are the overall safety database and safety study results for HPV vaccines?

Theme 7 - Aluminium:
Derived high-level question 7.0.: What is the knowledge about the safety of aluminium/AS04 as adjuvant?

Theme 8 - Data trustworthiness:
Derived high-level question 8.0.: Are the data for the EU referral procedure for HPV vaccines trustworthy?

Theme 9 - Assessment standards and integrity:
Derived high-level question 9.0.: How can it be demonstrated that signal detection, risk evaluation and decision-making have been performed to highest standards during the EU referral procedure for HPV vaccines?

Theme 10 - Benefit:
Derived high-level question 10.0.: What is the knowledge on the benefit and effectiveness of HPV vaccines?

Theme 11 - Benefit-risk balance:
Derived high-level question 11.0.: What does the statement 'the benefits outweigh the risks' mean?

Theme 12 - Further steps and research:
Derived high-level question 12.0.: What will the impact of the EU referral outcome be and will further research be done?

Table 2

Results of the utility evaluation of the media monitoring for the EU referral procedure on HPV vaccines in 2015[6]

EVALUATION METHOD	UTILITY
Obtaining feedback in person from colleagues within the EU regulatory network	- The cumulative look, together with the assessors, at the weekly considerations in early October 2015 confirmed that that all concerns voiced until then by the public relating to CRPS/POTS would be covered by the ongoing EU assessment. It was also confirmed that broader public concerns, such as those regarding aluminium-containing adjuvants, had been assessed previously. This provided reassurance that no additional data reviews would be necessary to respond to anticipated questions from the public. - Colleagues from EU member states noted that the provided weekly considerations enhanced communication preparedness at national level for possible questions from the public they had not thought of before, and helped putting national media attention in European and global context. - EMA communicators noted that they were guided by the derived questions as to which information items from the assessment procedure to include in the EMA Public Statement on the assessment outcome for website publication and dissemination to the EU regulatory network, its international partners, relevant patient and healthcare professional organisations and journalists. - EMA communicators noted that the derived questions guided them as to which information to include in the talking points for the EMA and EU member states for enabling immediate, accurate and consistent information in response to external requests, including those from journalists. Senior EMA colleagues considered the talking points helpful for preparing their attendance, upon invitation, of the discussion at the Danish parliament in December 2015.
Reviewing the EMA Public Statement summarising the assessment outcome of the EU procedure	- The review showed that using the derived questions enriched the EMA Public Statement by proactively including some detailed medical and methodological aspects for all identified themes in relation to HPV vaccines and CRPS/POTS, in addition to the usual reporting on assessment outcomes. - The review also showed that the EMA Public Statement contained respectful acknowledgement of the health status of CRSP/POTS patients and specific words expressing commitment and diligence towards the patients, different from the other summaries published by the EMA in 2015 which showed to be devoid of empathy.
Validating the predictive capacity of the derived questions by retrospective comparison with queries from journalists up to December 2015	- The comparison showed that all questions raised by journalists at the EMA press briefing at the day of concluding the assessment had been predicted by the derived questions and had hence been addressed in the talking points, enabling EMA colleagues to provide well-informed responses at the press briefing promptly. - The comparison showed that the derived questions predicted other recorded queries from journalists to the EMA, and had hence been addressed in the talking points, enabling EMA colleagues to provide well-informed responses promptly by phone or email.