

Frameworks for use of social media in pharmacovigilance

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Objectives

- Assess the current regulatory framework to identify potential gaps or areas for clarification
- Prepare recommendations on the use of social media in support of pharmacovigilance taking into account results from the WEB-RADR social media analytics and evaluation work packages
- Recommendations are to inform the EU Network's pharmacovigilance governance and future updates of Good Pharmacovigilance Practice (GVP) modules

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Some key questions

- What are obligations for MAHs to screen social media for ICSR collection (whether company sponsored or not)?
- What constitutes a valid report for adverse reaction reporting from social media?
- Should MAHs attempt to perform follow-up with users of social media for the purpose of ICSR reporting?
- What are obligations for MAHs to screen social media for the purpose of signal detection?
- Does the use of social media make a difference in pharmacovigilance obligations e.g. market research programmes, risk minimisation activities?

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What are social media

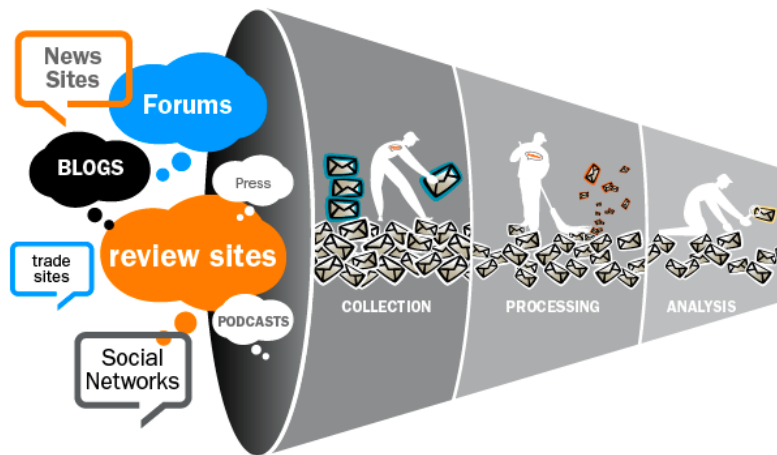
- A group of Internet-based applications that build on the ideological and technological foundations of Web 2.0 and that *allow the creation and exchange of user-generated content*.
- It employs mobile and web-based technologies to create highly interactive platforms via which individuals and communities share, co-create, discuss, and modify user-generated content*.

* Glossary Digital Single Market https://ec.europa.eu/digital-single-market/en/glossary#letter_s



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Social media in support of pharmacovigilance



- Social media as a **TOOLKIT** employed to
 - Operate pharmacovigilance activities and
 - Engage and interact with patient and healthcare communities
- Social media as an additional **DATA SOURCE** employed to
 - Research content and activity on social media

Social media as a TOOLKIT

Examples for social media as facilitator to engage

- **Patient support programme** – to create patient support groups and communities providing nurse advice, tips, motivation quotes and facilitating connections of patients with others in the community to join disease related conversations (e.g. MS, diabetes patients, glaucoma)
- **Market research programme** - to generate understanding and knowledge about a marketplace and consumer behaviour within it
- **Non-interventional study (primary data collection)** – to support interviews, questionnaires and patient follow-up as part of normal clinical practice
- **Risk minimisation** – to enrol patients, prescribers, pharmacies and healthcare facilities where prescription is only possible as part of a restricted programme or patients treated with a particular product may be asked to complete a brief survey or may be contacted at a later stage
- **Education** – to disseminate disease specific educational information aimed at patients to better understand their disease and to facilitate engagement with healthcare professionals to improve health outcomes



Recommendation

- Data resulting from the activities and which contribute to the safety profile of a medicinal product should be included within relevant regulatory procedures
- Reporting of suspected adverse reactions related to medicines and special situations:
 - Follow Guideline on good pharmacovigilance practices (GVP) - Module VI *“Collection, management and submission of reports of suspected adverse reactions to medicinal products”*
- Discussion on the identification of important identified and important potential risks, and missing information (i.e. safety concerns):
 - Follow GVP Module V *“Risk management systems”*
- Evaluation of the risk-benefit balance of a medicinal product at defined time points during the post-authorisation phase
 - Follow GVP Module VII *“Periodic safety update report”*

Social media as a DATA SOURCE

Examples for researching social media content or activities

- **Signal detection** – *looking for and/or identifying signals using data from any source*** such as identifying early signals related to rare adverse reactions or changes in the frequency, duration, severity or outcome of the adverse reaction
- **Signal validation** – to validate or reject signals that have arisen in other reporting systems
- **Non-interventional studies** – to evaluate patterns of the usage of medicines including potential for off-label use, lack of efficacy or use of medicines during pregnancy, to measure the effectiveness of risk management measures or to perform health outcome assessments

** Council for International Organizations of Medical Sciences (CIOMS). Report of CIOMS Working Group VIII on Practical Aspects of Signal Detection in Pharmacovigilance.

Geneva: CIOMS; 2010.



Recommendation

- Social media as additional data source should be considered as “secondary use of data” taking into account the following:
 - Social media are internet-based, unsolicited, real time data;
 - Content generated by individuals and communities with a primary objective to share, co-create, discuss, and modify information and experiences;
 - No planned interaction with social media users;
 - Use focuses on public health protection.



Recommendation

Signal detection and validation

- The use of social media data should be optional
- The reporting of suspected adverse reactions in the form of individual cases should not be required
- Follow-up with social media users should not be required
- Insights obtained through social media data which contribute to the safety profile of a medicinal product should be included within relevant regulatory procedures associated with the product including PSURs and Risk Management/ Minimisation Plans
- In case of an emerging safety issue, this should be notified it in writing to the relevant competent authority(ies) of Member State(s) and to the Agency
(by email to P-PV-emerging-safety-issue@ema.europa.eu within 2 working days of becoming aware of the issue)



Recommendation

Signal detection and validation

- Where social media data are used, the following should be defined and documented:
 - Purpose of the use of the social media data
 - Choice, demographics and generalisability of the social media data
 - Time period covered by the data set, including periodicity of updates and the approach to address evolving content (posts/discussions)
 - Data management method including data curation and data retention
 - Algorithms to be applied and frequency of analysis to be performed
 - Outcome of the signal detection and validation process, results and assessment of any findings
 - Safeguards of data (processing of personal data, security, access, ethical considerations)



Recommendation

- Social media data to **perform non-interventional studies (based on secondary use of data)**
 - Principles of applicable GVP Modules should be followed
 - **Reporting of suspected adverse reactions** in the form of individual cases should **not be required**
 - **Follow-up** with social media users should **not be required**
 - Reports of adverse events/reactions should be summarised as part of any **interim safety analysis** and in the **final study report** unless the protocol provides for different reporting
 - In case of an **emerging safety issue**, this should be **notified** it **in writing** to the relevant competent authority(ies) of Member State(s) and to the Agency
by email to P-PV-emerging-safety-issue@ema.europa.eu within 2 working days of becoming aware of the issue

Audience questions

Two questions for the audience

- Where do you see the biggest value of utilising social media in pharmacovigilance?
- Which areas do you see as not covered in depth within WEB-RADR?

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