Establishing a framework for the use of social media in pharmacovigilance in Europe; Drug Safety

(Survey results published as Lengsavath M, Dal Pra A, de Ferran A, Brosch S, Harmark L, Newbould V, Goncalves S. Social Media Monitoring and Adverse Drug Reaction Reporting in Pharmacovigilance: An Overview of the Regulatory Landscape. Therapeutic Innovation & Regulatory Science. 2016; 51(1): 125-131. Available from: doi: 10.1177/2168479016663264)

Sabine Brosch [1] , Anne-Marie de Ferran [2], Victoria Newbould [1], Diane Farkas [2]; Marina Lengsavath [2], Phil Tregunno [3]

[1] Surveillance and Epidemiology Services, Pharmacovigilance and Epidemiology Department, European Medicines Agency (EMA), 30 Churchill Place, Canary Wharf, London, E14 5EU, UK

[2] Sanofi, 1, avenue Pierre Brossolette - 91385 Chilly-Mazarin Cedex - France

[3] Medicines & Healthcare products Regulatory Agency, 10 South Colonnade, Canary Wharf , London, E14 4PU, UK

Corresponding author: sabine.brosch@ema.europa.eu

Table S4: Summary table survey on digital media monitoring

Country	Type of document	Status of document (final, draft)	Version date	Does the document include reference to AE reporting in the context of social media? Y/N	Does the document include specific risk management and communication provisions? Y/N	Does the document include reference to data privacy? Y/N	Summary of relevant section (English)	Comparison to GVP
In EEA								
26 EU countries	Legal provisions	Final V1	Sep-2014	Yes	No	Yes	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Greece, Hungary, Iceland, Ireland, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain - Only GVP guidelines are endorsed.	Equal

Country	Type of document	Status of document (final, draft)	Version date	Does the document include reference to AE reporting in the context of social media? Y/N	Does the document include specific risk management and communication provisions? Y/N	Does the document include reference to data privacy? Y/N	Summary of relevant section (English)	Comparison to GVP
France	ANSM Charter	Final	Mar-2014	Yes	Yes	Yes	Non promotional section of a website portal. x medicinal product (MP) information: Indicate if the MP is under a reevaluation of B/R following a safety notification x safety information: - Have a section with warning information related to ADR - Provide link of safety information of the product. -If operator invites the internet surfer to notify an ADR: ANSM link to be provided.	More than GVP
France	LEEM Guide	Final	May-2013	Yes	Yes	Yes	Legal framework guide applicable to immaterial communication for pharmaceutical industry Sheet n° 3: Issue link to the specificity of communication for the medicinal product (page 25-27) - Regulatory status on the communication on the medicinal products - PV obligations (Information related to PV obligations [incl. criteria for valid ICSR] and PV responsibility)	More than GVP
Germany	Literature Article	Final	2014	Yes	No	No	Legal view point by Michael Weidner in the cooperation with BPI (a German pharma industry association.[1] The pharmaceutical entrepreneur has to adjust its pharmacovigilance system accordingly in case of activity in social media. He has to ensure a regular check of the companies' owned internet presence especially regarding information on adverse effects, e.g. the companies' own presence on Facebook. The MAH is not obliged to remove reports on side effect of private Facebook users on the companies' owned website. It does not mean that the pharmaceutical entrepreneur has the obligation to screen the whole internet. The "Guideline on good pharmacovigilance practices" claims a regular monitoring of websites and social media, which are operated and maintained by the MAH. If users post or publish information on adverse effects, the regular requirements of §§ 63b and 63c German Drug Law (AMG) are in force. According to the regulation of § 63c sec. 2 No. 2 AMG, suspected cases of serious adverse drug reactions, which have occurred in a third party country, also must be recorded and reported. Private postings or comments in the internet of third party people, e.g. on private blogs are not falling into the responsibility of the MAH. In such cases it has to be adequate when the pharmaceutical entrepreneur meets his obligation to collect or report the ADR immediately, as soon as he is aware about the adverse effects. It is recommended to implement an internal process in advance to define who is responsible for the controlling function, which back-up rules are implemented and how the monitoring is organized.	Equal

Country	Type of document	Status of document (final, draft)	Version date	Does the document include reference to AE reporting in the context of social media? Y/N	Does the document include specific risk management and communication provisions? Y/N	Does the document include reference to data privacy? Y/N	Summary of relevant section (English)	Comparison to GVP
Italy	AIFA Letter[2]	Final	07-Feb-2014	Yes	No	No	National specificity : knowing that the reporting of cases by MAH should be done by regions of case occurrence, guidance is provided to pharmaceutical companies on how to report suspected adverse reactions when information about the reporter is not available (e.g. internet, digital media) "The new pharmacovigilance legislation provides that the authorization holders (MAH) carry out regular screening of the internet or digital media (web site , web page , blog, vlog , social networks , internet forums , chat rooms , health portal) to search for potential reports of suspected adverse drug reactions [..] Thus, in cases of suspected serious adverse reactions that are not possible to be sent to the Hospital of membership of the reporter, or to the Head of Pharmacovigilance healthcare facility (local HA), marketing authorization holders are allowed to enter directly such cases in EudraVigilance, within 15 days from date of receipt of the same. For the inclusion of these cases in EudraVigilance , with respect to information on the "primary source", simply fill in at least the field "Country". [..] "	More than GVP
Spain	FARMAINDUSTRIA Guide	Final	2009	No	No	Yes	FARMAINDUSTRIA´S STANDARD CODE ON PERSONAL DATA PROTECTION IN CLINICAL RESEARCH AND PHARMACOVIGILANCE Mentions the data protection process for the collection of the AE (section 5.2). Social media are not mentioned but only the company sponsored website.	Equal
Sweden	Läkemedelsindustriföreningen Guidance	Final	2-Dec-13	Yes	No	Yes	This is a general guidance document based on the requirements in GVP Module VI including aspects of the ABPI "Guidance notes on the management of adverse events and product complaints from digital media".	More than GVP
United Kingdom	ABPI Guidance	Final	8-Apr-13	Yes	Yes	Yes	These guidance notes refer to the collection and management of AE/PC from digital media, which has been implemented for legitimate business purposes in the UK. This includes company-sponsored websites (eg www.pharmaceuticalcompany.co.uk), all company-owned social media sites used for business campaigns and use of non-company-sponsored websites. These guidance notes are relevant for all company employees using digital media, including persons retained by way of contract with third parties. Company-Sponsored: A website is considered to be company-sponsored if it is owned, paid for Website and/or controlled by the company. Control means that the company has authority over the final content. A donation (financial or otherwise) to an organisation/site by a marketing authorisation holder does not	More than GVP

Country	Type of document	Status of document (final, draft)	Version date	Does the document include reference to AE reporting in the context of social media? Y/N	Does the document include specific risk management and communication provisions? Y/N	Does the document include reference to data privacy? Y/N	Summary of relevant section (English)	Comparison to GVP
							constitute ownership, provided that the marketing authorisation holder does not control the final content of the site. A company may sponsor a 'page' on a website/platform that they do not own (eg a social media or micro-blogging sites). If the company has control over the content of a sponsored page, it is considered company sponsored. 5.3 Data privacy Notice should be given on company-sponsored sites that user-generated information deemed to be an AE/PC will be collected by the company in order to meet legal obligations. It is advisable to explain why such information is beneficial for the protection of public health. It should also be noted that the company may follow-up directly with the individual who generated the AE/PC information in order to gain more information. 7. Collection and follow-up of AEs and PCs from company-sponsored sites Company-sponsored sites used for external communication can be designed to facilitate PV. For example, sites can include free text fields or provide links or access to internal/external reporting tools which allow users to report adverse events. Other components such as the 'Terms and conditions for use' or a formal site registration process can be used to obtain information that enables MAHs to identify and contact users to validate and follow-up on safety information. A moderation process can be implemented which can include actions to be taken in response to safety information being posted. Blogging policies and disclaimers can also be used. These features and processes help companies meet their responsibilities over safety information generated on company-sponsored sites, particularly in relation to safety of their medicines. […] It is also essential that the responsible person captures the date the information was posted on the site and the date that anyone from the company or working on behalf of the company first becomes aware of the information. The following information should be collected if possible: • an identifiable patient • a suspect drug • an adverse event • an identifiable reporter. Contact details are needed for a reporter to be considered identifiable; an email or a screen name that allows contact to be initiated would be acceptable. The country where the information was received or where the review took place	

Country	Type of document	Status of document (final, draft)	Version date	Does the document include reference to AE reporting in the context of social media? Y/N	Does the document include specific risk management and communication provisions? Y/N	Does the document include reference to data privacy? Y/N	Summary of relevant section (English)	Comparison to GVP
							should be noted if the country of the primary source is unknown. […] It is recommended that a screen shot is saved and used as the source documentation. Attempts should be made to obtain follow-up information relating to AE/PC in line with the company's procedures. The company should have procedures for inclusion of non-valid cases in their signal detection activities 8. Collection and follow-up of AEs and PCs from non-company sponsored […] Companies may release company-sponsored software applications (apps) eg for smart phones and tablet computers where an app user (eg a patient or healthcare professional) can post comments on the noncompany- sponsored distribution platform (eg App Store) through which the app is made available. The MAH would not routinely be required to monitor review comments posted on these app distribution platforms which are considered non-company-sponsored digital media. However, should the MAH periodically review these comments for other purposes, any AE/PC identified should be collected and reported appropriately. As there is no legal requirement to monitor non-company-sponsored sites, Day 0 is the day the MAH first becomes aware of the AE/PC. Content generated via the app itself is under the management and responsibility of the MAH sites. MAHs may become aware of an AE/PC on non-company-sponsored public portals or micro-blogging sites where the content can be viewed by many site users and MAHs have a responsibility to follow-up these reports. In this situation, the MAH should consider the most appropriate method of follow-up to protect patient confidentiality. For example, the MAH may direct the site user (ie AE/PC reporter) to contact the company via the company website, email or phone to provide further AE/PC information.	
Outside EEA								
Australia	Local Health Authority	Final	June 2014	Yes	No	Yes	Sponsors should regularly screen internet or digital media [1] under their management or responsibility, for potential reports of suspected adverse	Equal

[1] Although not exhaustive, the following list should be considered as digital media: web site, web page, blog, vlog, social network, internet forum, chat room, health portal.

Country	Type of document	Status of document (final, draft)	Version date	Does the document include reference to AE reporting in the context of social media? Y/N	Does the document include specific risk management and communication provisions? Y/N	Does the document include reference to data privacy? Y/N	Summary of relevant section (English)	Comparison to GVP
	PV Guideline						reactions (ARs). This includes digital media that is owned, paid for and/or controlled by the sponsor[2]. The frequency of the screening should allow for valid ARs to be reported within the appropriate reporting timeframe based on the date the information was posted on the internet site/digital medium. Sponsors may also consider utilising their websites to facilitate the collection of reports of suspected ARs. If a sponsor becomes aware of a report of a suspected AR described in any non-company sponsored digital medium, the report should be assessed to determine whether it qualifies for reporting. If so, it should be reported according to the timeframes specified in this document. In relation to cases from the internet or digital media, the identifiability of the reporter refers to the existence of a real person, that is, it is possible to verify the contact details of the reporter (e.g., an email address under a valid format has been provided).	
Egypt	GVP for Arab Countries	Final	Dec 2014	Yes	No	No	VI.B.1.1.4. Information on suspected adverse reactions from the internet or digital media Marketing authorisation holders should regularly screen internet or digital media[3] under their management or responsibility, for potential reports of suspected adverse reactions. In this aspect, digital media is considered to be company sponsored if it is owned, paid for and/or controlled by the marketing authorisation holder[4]. The frequency of the screening should allow for potential valid ICSRs to be reported to the medicines authorities within the appropriate reporting timeframe based on the date the information was posted on the internet site/digital medium. Marketing authorisation holders may also consider utilising their websites to facilitate the collection of reports of suspected adverse reactions (See VI.C.2.2.1) If a marketing authorisation holder becomes aware of a report of suspected adverse reaction described in any non-company sponsored digital medium, the report should be assessed to determine whether it qualifies for reporting.	Equal

2 A donation (financial or otherwise) to an organisation/site by a sponsor does not constitute ownership, provided that the sponsor holder does not control the final content of the site

3 Although not exhaustive, the following list should be considered as digital media: web site, web page, blog, vlog, social network, internet forum, chat room, health portal.

4 A donation (financial or otherwise) to an organisation/site by a marketing authorisation holder does not constitute ownership, provided that the marketing authorisation holder does not control the final content of the site

Country	Type of document	Status of document (final, draft)	Version date	Does the document include reference to AE reporting in the context of social media? Y/N	Does the document include specific risk management and communication provisions? Y/N	Does the document include reference to data privacy? Y/N	Summary of relevant section (English)	Comparison to GVP
							Unsolicited cases of suspected adverse reactions from the internet or digital media should be handled as spontaneous reports. The same reporting time frames as for spontaneous reports should be applied (see VI.B.7). In relation to cases from the internet or digital media, the identifiability of the reporter refers to the existence of a real person, that is, it is possible to verify the contact details of the reporter (e.g., an email address under a valid format has been provided). If the country of the primary source is missing, the country where the information was received, or where the review took place, should be used as the primary source country.	
Korea, republic of	Privacy act	Final	07 Aug 2014	No	No	Yes	Law No. 11 990, 2013.8.6 revised in 2014 Data privacy law requiring consent or information to the subject when sensitive information is being collected. Article 23 (Limitation on the processing of sensitive personal information) Processor of personal information shall not process the data on ideological · beliefs, trade union · register · withdrawal of political parties, political opinions, health, information regarding the sex, other personal information which are likely to significantly invade the privacy of data subject, covered by Presidential Decree (hereinafter referred as "sensitive information") However, the following shall not apply in the case which include to any of the subparagraphs. 1. If additional explicit consent and consent for processing other personal information were obtained from data subject, after informing Article 15 paragraph 2[5] or Article 17 paragraph 2[6].	Less on AE reporting – More specific on personal data protection : law requiring consent or information to the subject when sensitive

[5] Article 15 paragraph 2 - Processor of personal information shall notify the following matters to the data subject when acquired the consent. If any of the details following is changed, it shall be informed and consent required.

1. Purpose of collection · use of personal Information
2. The entry of personal information to be collected
3. Use and retention period of collected personal information
4. Data subject's right not to consent to such collection and disadvantages, if any, if data subjects choose not to consent

Country	Type of document	Status of document (final, draft)	Version date	Does the document include reference to AE reporting in the context of social media? Y/N	Does the document include specific risk management and communication provisions? Y/N	Does the document include reference to data privacy? Y/N	Summary of relevant section (English)	Comparison to GVP
							2. If the laws require or allow the processing of sensitive information.	information is being collected.
Saudi Arabia	SFDA local guidelines	Final	Sept 2015	Yes	No	YES	VI.B.1.1.4. Information on suspected adverse reactions from the internet or digital media Marketing authorisation holders should regularly screen internet or digital media[7] under their management or responsibility, for potential reports of suspected adverse reactions. In this aspect, digital media is considered to be company sponsored if it is owned, paid for and/or controlled by the marketing authorisation holder[8]. The frequency of the screening should allow for potential valid ICSRs to be reported to the SFDA within the appropriate reporting timeframe based on the date the information was posted on the internet site/digital medium. Marketing authorisation holders may also consider utilising their websites to facilitate the collection of reports of suspected adverse reactions. If a marketing authorisation holder becomes aware of a report of suspected adverse reaction described in any non-company sponsored digital medium, the report should be assessed to determine whether it qualifies for reporting. Unsolicited cases of suspected adverse reactions from the internet or digital media should be handled as spontaneous reports. The same reporting time frames as for spontaneous reports should be applied (see VI.B.7). In relation to cases from the internet or digital media, the identifiability of the reporter refers to the existence of a real person, that is, it is possible to verify the contact details of the reporter (e.g., an email address under a valid format has	Equal

[6] Article 17 paragraph 2 (1 information which shall be provided to data subject is added) Information on any person or company which will receive personal information

[7] Although not exhaustive, the following list should be considered as digital media: web site, web page, blog, vlog, social network, internet forum, chat room, health portal.

[8] A donation (financial or otherwise) to an organisation/site by a marketing authorisation holder does not constitute ownership, provided that the marketing authorisation holder does not control the final content of the site

Country	Type of document	Status of document (final, draft)	Version date	Does the document include reference to AE reporting in the context of social media? Y/N	Does the document include specific risk management and communication provisions? Y/N	Does the document include reference to data privacy? Y/N	Summary of relevant section (English)	Comparison to GVP
							been provided). If the country of the primary source is missing, the country where the information was received, or where the review took place, should be used as the primary source country.	
South Africa	MCC Guidance	Final	Aug 2014	Yes	No	Yes	Applicants should regularly screen websites under their management or responsibility for potential ADR case reports. The frequency of the screening should allow for potential valid ADRs to be reported to the MRA within the appropriate expedited timeframe based on the date the information was posted. Unsolicited cases from the Internet should be handles as spontaneous reports. For determination of reportability, the same criteria should be applied as for cases provided via other ways. In relation to such cases from the Internet, e.g. e-mail, identifiability of the reporter refers to the existence of a real person, i.e. it should be possible to verify that the patient and the reporter exist (e.g. a valid e-mail address has been provided). Contact details should only be use for Pharmacovigilance purposes.	Equal
Turkey	Guideline on Good Pharmacovigilance Practices (GPVP) Module I – Management and reporting of adverse drug reactions	Final	12.06. 2014	Yes	No	Yes	2.1.1.4 Information on suspected adverse reactions from the Internet or digital media Marketing authorization holders should regularly screen the Internet/digital media under their management or responsibility, such as web sites, web pages, blogs, vlogs, social networks, Internet forums, chat rooms, or health portals, for potential reports of suspected adverse reactions. In this aspect, digital media is considered to be company sponsored if it is owned, paid for and/or controlled by the marketing authorization holder. A donation (financial or otherwise) to an organization/site by a marketing authorization holder does not constitute ownership, provided that the marketing authorization holder does not control the final content of the site. The frequency of the screening should allow for potential valid ICSRs to be reported to TÜFAM within the appropriate reporting timeframe based on the date the information was posted on the Internet site/digital medium. Marketing authorization holders should also utilize their own websites to facilitate the collection of reports of suspected adverse reactions (see 3.1.1).	Equal

Country	Type of document	Status of document (final, draft)	Version date	Does the document include reference to AE reporting in the context of social media? Y/N	Does the document include specific risk management and communication provisions? Y/N	Does the document include reference to data privacy? Y/N	Summary of relevant section (English)	Comparison to GVP
							If a marketing authorization holder becomes aware of a report of suspected adverse reaction described in any non-company sponsored digital medium, it should assess the report to determine whether it qualifies for reporting. Unsolicited cases of suspected adverse reactions from the Internet or digital media should be handled as spontaneous reports. The same reporting time frames as for spontaneous reports should be applied. In relation to cases from the Internet or digital media, the identifiability of the reporter refers to the existence of a real person, that is, it is possible to verify the contact details of the reporter (e.g., an email address under a valid format has been provided).	
Turkey	AIFD Code of Practice of Good Promotion and Good Communication	Final V5	Jan 2014	Yes	No	Yes	Reference to accuracy of data and rules/ recommendations for company sponsored websites. Reference to AE collection from digital media. ANNEX II: AIFD USER GUIDE ON DIGITAL COMMUNICATION APPLICATIONS IN THE PHARMACEUTICAL SECTOR 1. Principle of Transparency and General Rules 1.2. Personal information collected from visitors should be kept confidential. The website should be arranged and managed in accordance with national laws and regulations and international rules with regard to the protection of confidentiality, safety and privacy of personal information. 3. Websites Prepared for Patients and the General Public, Not Comprising Any Promotion and Aimed at Providing Information on Health 3.7. The statement “Information on this website shall not replace consultation with a physician or pharmacist.” Should be included on pages intended for patients and relevant pages should contain, at all times, the recommendation reading, “Consult a physician and/or pharmacist for further information”. 3.8. Companies should stay clear of discussions involving individuals’ health problems in e-mail correspondence received from patients or the general public originating from websites, and advise such persons to consult with their physicians or pharmacists. 3.9. Websites allowing submission of free text messages should be regularly monitored for potential adverse event reports. 4. Websites Prepared for Healthcare Professionals, Comprising Also Product Promotion and Intended for Promotion or Training	More than GVP

Country	Type of document	Status of document (final, draft)	Version date	Does the document include reference to AE reporting in the context of social media? Y/N	Does the document include specific risk management and communication provisions? Y/N	Does the document include reference to data privacy? Y/N	Summary of relevant section (English)	Comparison to GVP
							4.4. Electronic mailing systems used at company websites should be regularly monitored for potential adverse reports. 4.11. If a section is included where physicians can exchange views, the moderation rules for this section should be clearly stated in the website's terms and conditions for use (that the comments will be monitor to verify their compliance with the Regulation and the Code of Promotional Practice, the route to be pursued for adverse event reports, etc.). 6. Use of Social Media Applications 6.9. When a negative comment is noticed by a company employee against the company or its products, he/she should notify appropriate designated functions within the company (social media responsible, corporate communications, compliance officer etc.); if the message is related to an adverse reaction, the officer responsible for drug safety should be strictly notified thereof. 6.14. When an adverse reaction report is detected in a digital environment, concerning any company product, the Drug Safety Department should be promptly notified, following company procedures. Question 5 – Can a pharmaceutical company to open a Facebook account open to the general public, which does not comprise products and names of molecules but is intended to raise awareness only on a disease? Answer 5 – Pharmaceutical companies may prepare pages for raising awareness on a disease, where the purpose of the page is clearly indicated, names of products and molecules are not included, no product promotion is made or any message, news and image that may be associated with product promotion is included. The company should clearly indicate that it has sponsored this page. Free text boxes (areas where comments are made) should be regularly followed by the pharmacovigilance officer of the sponsoring company. Any debate on drugs on Facebook shall be against the AIFD Code of Promotional Practice and will be regarded as "promotion to the general public." In case of adverse event report on the page, information should be duly compiled in line with relevant laws and regulations and company rules and the report should be submitted to relevant authorities. Question 14 – The fact that only invited persons may join the group in closed Facebook groups, that the members cannot invite another member, that the correspondence of the members about this group does not appear on their homepage, enables the protection of information and prevent it from being	

Country	Type of document	Status of document (final, draft)	Version date	Does the document include reference to AE reporting in the context of social media? Y/N	Does the document include specific risk management and communication provisions? Y/N	Does the document include reference to data privacy? Y/N	Summary of relevant section (English)	Comparison to GVP
							shared. Can we create such closed groups for a specific target audience, both internally in the company and with a closed Facebook group of physicians? Answer 14 – Provided that they comply with the AIFD Code of Promotional Practice, closed groups and discussion groups can be opened and sponsored. Groups comprising presentations or discussions with product promotion can only include physicians, dentists and pharmacists. The sponsoring company shall be kept responsible for ensuring that the comments made by colleagues within the group remain within the boundaries of the code of promotional practice and the Regulation. It may not be possible to delete the messages written by others in environments such as Facebook and the company which has opened or sponsored the site shall be responsible for the outcomes. In case of mention of an adverse effect within a closed group that needs to be followed in terms of pharmacovigilance, the sponsor or the founding pharmaceutical company shall be responsible for submitting the reports to the relevant authorities within the timeframe designated in the provisions of the Pharmacovigilance Regulation.	
United States of America	FDA Guidance	Draft Guidance	Jan 2014	No	No	Yes	Fulfilling regulatory requirements for post marketing submissions of interactive promotional media for prescription human and animal drugs and biologics	Guidance related to promotional media – no reference to AE reporting
United States of America	FDA Guidance	Draft Guidance	June 2014	No	No	Yes	Internet Social Media Platforms with character space limitations-Presenting Risk and Benefit Information for prescription drugs and medical devices	Guidance related to promotional media – no reference to AE reporting
United States of America	FDA Guidance	Draft Guidance	June 2014	No	Yes	No	Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices	Guidance related to communication – no reference to AE reporting

[1] Michael Weidner, Arzneimittelwerbung im Bereich "Social Media" *Pharma Recht* 6/2014, S241

[2] Communication of the italian medicines agency on the management of italian reports of suspected adverse reactions - In the national pharmacovigilance network http://www.agenziafarmaco.gov.it/it/content/nuove-modalit%C3%A0-di-gestione-le-segnalazioni-di-adr-aggiornamento-07022014