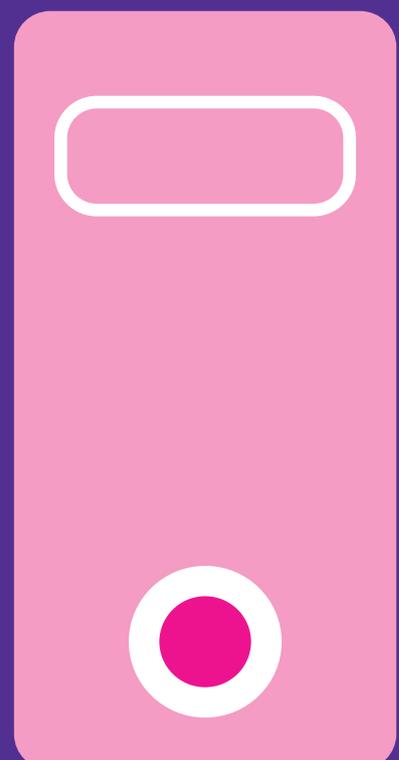


***Guidance notes*** on the  
management of adverse events  
and product complaints from  
digital media



# ***Guidance notes*** on the management of adverse events and product complaints from digital media

ABPI Pharmacovigilance Expert Network

## **Approval Status**

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## 1. Introduction

Digital media is used by individuals and organisations as a component of overall communication with patients and customers to create or raise awareness about diseases and treatments or for other strategic objectives. Pharmaceutical companies also use digital media for corporate awareness, clinical trial enrolment, and patient support programmes.

Consideration of company values, public expectation, legal and policy requirements are necessary for successful participation in the digital media environment. Additionally, Marketing Authorisation Holders (MAH) have an obligation to monitor, collect and manage product safety (or quality) information which may be generated through digital media. The following notes provide guidance on the monitoring and management of adverse events (AE) or product complaints (PC) arising from company-sponsored and non-company-sponsored digital media. The term ‘monitor’ within this document refers to monitoring for AE/PC.

These guidance notes have been developed by the ABPI Pharmacovigilance Expert Network (PEN) and shared with the Medicines and Healthcare products Regulatory Agency (MHRA). They are compiled based on current legislative requirements. However, it is the responsibility of each MAH to decide in the context of their circumstances how to apply these informal guidance notes. The ABPI and MHRA reserve the right to adopt an alternative position should they be called upon to discuss pharmacovigilance (PV) and digital media.

This document is provided by the ABPI for information purposes only and is not intended and should not be construed as regulatory or legal advice.

Companies must ensure that all their activities comply with the appropriate legislative requirements for PV and with the *ABPI Code of Practice for the Pharmaceutical Industry* (see Section 3 below). The Prescription Medicines Code of Practice Authority (PMCPA) which administers the Code at arm’s length from the ABPI has issued informal guidance about digital communications. Both are available from [www.pmcpa.org.uk](http://www.pmcpa.org.uk).

## 2. Scope

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](http://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.

## 3. Legal framework and guidance

Companies must comply with all applicable legislation. In Europe, two pieces of legislation underpin PV expectations: Regulation 726/2004 (as amended by Regulation 1235/2010) and Directive 2001/83/EC (as amended by Directive 2010/84/EU)<sup>1</sup>. Operational aspects, including the Commission Implementing Regulation 520/2012, are detailed in the associated GVP guidance<sup>2</sup>. Pharmaceutical companies should also comply with requirements in the *ABPI Code of Practice for Pharmaceutical Industry*<sup>3</sup>. The PMCPA’s

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<sup>1</sup> European Medicines Agency 2013. The EU pharmacovigilance system. Available at: [http://ec.europa.eu/health/human-use/pharmacovigilance/index\\_en.htm](http://ec.europa.eu/health/human-use/pharmacovigilance/index_en.htm)

<sup>2</sup> European Medicines Agency 2013. Good pharmacovigilance practices. Available at: [www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document\\_listing/document\\_listing\\_000345.jsp](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000345.jsp)

<sup>3</sup> The ABPI Code of Practice for the Pharmaceutical Industry 2012. Available at: [www.pmcpa.org.uk/thecode/Pages/default.aspx](http://www.pmcpa.org.uk/thecode/Pages/default.aspx)

informal guidance on digital communications<sup>4</sup> should also be considered. GVP Module VI states<sup>5</sup>:

*Marketing authorisation holders should regularly screen internet or digital media<sup>6</sup> 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<sup>7</sup>. The frequency of the screening should allow for potential valid individual case safety reports (ICSRs) to be reported to the competent 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.*

*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 (eg 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.*

### **Council for International Organization of Medical Sciences (CIOMS)**

Section II d (p.55) of *Current challenges in pharmacovigilance: pragmatic approaches*, (report of CIOMS Working Group V) states<sup>8</sup>:

*A procedure should be in place to ensure daily screening by a designated person(s) of the website(s) in order to identify potential safety case reports.*

*The working group does not believe it necessary for regulators or companies routinely to ‘surf’ the internet beyond their own sites for individual spontaneous reports.*

### **ABPI Code of Practice for the Pharmaceutical Industry**

The ABPI Code prohibits the advertising of Prescription Only Medicines (POMs) to the public. Any promotional material about POMs directed to a UK audience must comply with the relevant requirements of the ABPI Code including therapeutic area/disease awareness websites sponsored by companies.

There are similar provisions in UK and European law. The ABPI Code allows factual and balanced information about POMs to be provided to the public. Such information must not raise unfounded hopes of successful treatment or be misleading about the safety of a medicine. Detailed information about what information can be provided is given in the ABPI Code. Informal guidance on digital communications and the ABPI Code was published by the PMCPA in 2012<sup>9</sup>.

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<sup>4</sup> PMCPA 2012. Informal guidance on digital communications. Available at: [www.pmcpa.org.uk/advice/digital%20communications/Pages/default.aspx](http://www.pmcpa.org.uk/advice/digital%20communications/Pages/default.aspx)

<sup>5</sup> European Medicines Agency 2013. Good pharmacovigilance practices Module VI, Section VI.B.1.1.4. Available at: [www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2012/06/WC500129135.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/06/WC500129135.pdf)

<sup>6</sup> Although not exhaustive, the following list should be considered as digital media: website, web page, blog, vlog, social network, internet forum, chat room, health portal.

<sup>7</sup> 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.

<sup>8</sup> CIOMS 2001. Report of CIOMS Working Group V. Current challenges in pharmacovigilance: a pragmatic approach, Section II d. See: [www.cioms.ch/index.php/publications/available-publications?task=view&id=23&catid=54](http://www.cioms.ch/index.php/publications/available-publications?task=view&id=23&catid=54)

<sup>9</sup> PMCPA 2012. Informal guidance on digital communications. Available at: [www.pmcpa.org.uk/advice/digital%20communications/Pages/default.aspx](http://www.pmcpa.org.uk/advice/digital%20communications/Pages/default.aspx)

## 4. Social media activities

Social media activities by companies fall into three broad categories which have varying degrees of complexity, associated issues and requirements. In addition, compliance with the ABPI Code is required. Please note that reporter identity (eg healthcare professional or consumer) does not change pharmacovigilance requirements.

### 4.1 Listening

Monitoring social media sites allows a company to 'listen to' or 'see' what the public are discussing, saying or sharing about the company itself, diseases, conditions, and treatment options. This type of activity can be prospective or retrospective and is predominately performed in non-company-sponsored sites, but can also take place in company-sponsored sites. For example, a MAH may 'listen to' user-generated content from specific social media sites or from specific users of that social media site (eg key health care opinion leaders or patient group representatives) for a defined period of time. In addition to 'listening' on specific sites and/or specific users, companies also use automated tools to detect keywords across the internet or specified sites. Whatever form the listening activity takes, the objectives and specifics of such activities should be outlined in the project plan, see Section 5 below. During the listening activity, the company should declare its presence by registering on the site using the company name where possible.

If a company chooses to 'listen in' at non-company-sponsored sites, it is recommended that the relevant pages of the site should be monitored for AE/PC for the period of the listening activity only.

### 4.2 Broadcasting

Digital media (usually if company sponsored) may allow companies to initiate one-way communication to share messages with the public, where interactive dialogue is not permitted or practical. This type of activity should only allow one-way communication of information (ie from the company to the public) and it is important to ensure the site does not allow interactive dialogue or the creation of user-generated content. The site should also be checked to ensure that dialogue facilities do not exist (ie visitor comments/blogs). The ability of visitors to comment through other sites, platforms or technologies that are not controllable by the company, such as web annotation tools that allow users to post and read comments on websites, do not conflict with this recommendation.

If a 'Contact us' link is provided on a company-sponsored site, the project owner must document where the link is routed to (eg medical information department), provide evidence that the link is working via testing and identify who will be responsible for monitoring any correspondence received and the frequency of monitoring. It is also important to document how AE/PC will be managed, see Section 5.

### 4.3 Engaging

Engaging, exchanging and participating in interactive communication with the public. This activity is performed in company-sponsored and non-company-sponsored sites. For example, a company may decide to engage with patient groups or opinion leaders to gather insights into a particular disease state or class of treatments. The objectives and specifics of the project should be outlined in the project plan and each project should have a project owner, see Section 5. During engagement activity on a non-company-sponsored site, the company should be transparent and declare its presence.

For users to join a company-sponsored social media site, appropriate permissions and disclaimers should be presented in advance in the terms and conditions. For example, consent should be given for the company to follow-up with a user should they report AE/PC. It should also be made clear that personal information may be processed on internal company databases and sent to regulators.

Companies sponsoring 'interactive' social media sites (or pages) must monitor the entire content on an ongoing basis including company websites where visitors may be able to leave messages or request information, see Section 4.2. When pre-publication moderation is carried out, it should help ensure compliance with the ABPI Code and other regulatory obligations. Monitoring should be frequent enough

to ensure regulatory obligations can be met and daily monitoring for the duration of the project should be considered.

Companies may wish to use online surveys sent to site members for data gathering and it is recommended that data is collected from such activities (eg uploaded and stored on a company server). All information received in this way should be monitored daily for AE/PC.

If a company participates in engagement type activities in non-company-sponsored sites, it is recommended that the site is monitored daily for AE/PC only for the duration of the project.

## 5. General points for consideration

### 5.1 Project management and oversight

Consultation within the company is strongly recommended prior to initiation of a digital media project, relevant groups include: pharmacovigilance, legal, data protection, compliance, medical information, corporate communications and market research. The European Qualified Person for Pharmacovigilance (EU-QPPV) should have oversight of all projects that have potential to generate safety information.

It is recommended that each digital media project has a project owner responsible for training and oversight of any activities of engaged third parties. In addition, for company-sponsored sites a 'digital spokesperson' should be appointed who manages the content of the site according to a defined moderation and escalation process. It is also advisable that expertise exists within the company (or via a third party) of emerging digital media platforms and that the online evolution of the channel (or its termination) is reviewed.

It is recommended that each social media project has a project plan which includes the following:

- the objective of the project
- name (and back-up) of project owner
- name (and back-up) of digital spokesperson
- AE/PC monitoring plan and coverage
- AE/PC reconciliation and quality control
- review schedule
- training provided
- vendor contacts etc
- exit strategy.

### 5.2 Declaration of company involvement and responsibilities

The company's involvement in a social media site must be transparent to users. If the site is owned by the company, this must be disclosed. It is also recommended that the company disclose the length of time it intends to sponsor the site (if known) and how it intends to screen and use any user-generated content.

It is advisable that company-sponsored sites provide a mechanism for the user to report an AE/PC to the company eg providing online reporting forms or contact details for direct communication (eg phone numbers, email address)<sup>10</sup>. It may be appropriate to provide links to regulatory authority reporting schemes such as the MHRA Yellow Card scheme.

Where possible, content should be removed or locked (inhibiting further posts) once the objectives have been reached.

If a third party vendor is involved in the social media site, it is recommended that the contract delineates the responsibilities of each party (especially regarding PV obligations) and gives rights for the MAH to audit the vendor.

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<sup>10</sup> European Medicines Agency 2013. Good pharmacovigilance practices Module VI, Section VI.B.1.1.4. Available at: [www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2012/06/WC500129135.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/06/WC500129135.pdf)

Notice should be given on company-sponsored sites that the company reserves the right not to publish any user-generated content especially information that would violate any applicable laws and comments which are deemed to be abusive, obscene, inflammatory, or offensive.

### 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<sup>12</sup>.

## 6. Training

MAHs should ensure that all staff involved in the social media channel are appropriately trained for performing PV-related activities. Individuals responsible for monitoring the digital media for AE/PC should receive specific training on the identification of AE/PC and other safety information relating to a MAH product, for example, off-label use, pregnancy, lack of effect and overdose, see Annex 2, special reporting situations. In addition, staff must be trained on who to report the information to, how and within what timeframes. All training should be documented. The above also applies to any persons retained by way of a contract with third parties.

## 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.

MAHs conducting 'listening', 'broadcasting' and 'engaging' activities on company-sponsored websites have an obligation to collect and follow-up on AE/PC associated with their products. Details of all AE/PC for the company's products (branded or generic) should be collected and documented, regardless of:

- seriousness of the event
- whether there is an identifiable reporter
- whether the AEs are listed in the product's Summary of Product Characteristics (SmPC)
- whether a definite causal relationship or link to the product has been stated
- whether the individual has already reported the event to a competent authority or says they have reported it to the company.

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

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<sup>12</sup> ABPI 2013. Guidance on UK data protection in post-marketing pharmacovigilance. Available at: [www.abpi.org.uk/our-work/library/guidelines/Pages/data-protection.aspx](http://www.abpi.org.uk/our-work/library/guidelines/Pages/data-protection.aspx)

- 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 should be noted if the country of the primary source is unknown.

In addition to AE/PC, information should also be collected in order to comply with the requirements for reporting in special situations, see Annex 2<sup>13</sup>.

All AE/PC identified by company employees or any individual representing or acting on the company's behalf need to be captured and reported to the company's PV department. It is recommended that this is within one business day of receipt. A confirmation of receipt may be issued. 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 sites

If a company (or contracted third party) chooses to participate in activities in non-company-sponsored sites and identifies an AE/PC, this should be forwarded to the company PV department. It is recommended that this is within one business day. See Section 3 for legal background.

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 non-company-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<sup>14</sup>.

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<sup>14</sup>.

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<sup>13</sup> European Medicines Agency 2013. Good pharmacovigilance practices Module VI, Section VI.B.6. Available at: [www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2012/06/WC500129135.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/06/WC500129135.pdf)

<sup>14</sup> MHRA Good Pharmacovigilance Practice Consultative Committee 2012. Questions for the Committee Meeting in November 2012. Available at: [www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodPharmacovigilancePractice/GoodPharmacovigilancePracticeConsultativeCommittee/index.htm](http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodPharmacovigilancePractice/GoodPharmacovigilancePracticeConsultativeCommittee/index.htm)

## Annex 1: Abbreviations

Abbreviation	
ABPI	The Association of the British Pharmaceutical Industry
ADR	Adverse Drug Reaction
AE	Adverse Event
CIOMS	Council for International Organization of Medical Sciences
EMA	European Medicines Agency
EU	European Union
EU- QPPV	European Qualified Person for Pharmacovigilance
GVP	Good Vigilance Practice
ICSR	Individual Case Safety Report
MAH	Marketing Authorisation Holder
MHRA	Medicines and Healthcare products Regulatory Agency
PC	Product Complaint
PEN	ABPI Pharmacovigilance Expert Network
PMCPA	Prescription Medicine Code of Practice Authority
POM	Prescription Only Medicine
PSUR	Periodic Safety Update Report
PV	Pharmacovigilance
RMP	Risk Management Plan
SmPC	Summary of medicinal Product Characteristics

## Annex 2: Definitions

The definitions are taken from the *Good vigilance practice (GVP) guidance, where appropriate*<sup>15</sup>.

Term	Meaning
<b>Adverse Drug Reaction</b>	<p>A response to a medicinal product which is noxious and unintended. Response in this context means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility.</p> <p>Adverse reactions may arise from use of the product within or outside the terms of the marketing authorisation or from occupational exposure. Conditions of use outside the marketing authorisation include off-label use, overdose, misuse, abuse and medication errors.</p>
<b>Adverse Event</b>	<p>Any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have to have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign (eg an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.</p>
<b>Company-Sponsored Website</b>	<p>A website is considered to be company-sponsored if it is owned, paid for 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 constitute ownership, provided that the marketing authorisation holder does not control the final content of the site.</p> <p>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.</p>
<b>Non-Company-Sponsored website</b>	<p>A website is considered to be non-company-sponsored if the site is not owned, paid for or controlled by the company. For such a site, there must be no possibility that the pharmaceutical company has been able to exert any influence or control the final content of the site. A donation (financial or otherwise) to an organisation/website by a pharmaceutical company does not constitute sponsorship provided that the pharmaceutical company does not control the final content of the site.</p>
<b>Product Complaint</b>	<p>A complaint specific to the product itself, its supporting devices or packaging, as opposed to its effect on the patient. Examples include damaged or missing tablets; wrong strength or colour of tablets; damaged packaging; a label that cannot be read; a liquid that should be clear but is cloudy or contains unexpected particles; a bent needle; a broken syringe; a missing patient information leaflet, or the identification of a potentially counterfeit medicine.</p>

<sup>15</sup> European Medicines Agency 2013. Good pharmacovigilance practices. Available at: [www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document\\_listing/document\\_listing\\_000345.jsp](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000345.jsp)

Term	Meaning
<b>Special Reporting Situations</b>	<ul style="list-style-type: none"><li>• Use during pregnancy, i.e. drug exposure to a foetus in utero (whether the foetus is exposed via the mother taking the product or transmission via semen following paternal exposure)</li><li>• Exposure to a drug during breast-feeding/lactation</li><li>• Overdose (whether intentional, accidental or prescribed)</li><li>• Drug abuse or misuse</li><li>• Medication errors (including dispensing errors, accidental exposure, maladministration, etc.)</li><li>• Unapproved or off-label use (i.e. intentional medical use of a product not in accordance with the authorised product information) including off-label use in children or the elderly.</li><li>• Reports of lack of therapeutic effect or other product complaints associated with an adverse event, including suspected use of counterfeit medicine/ tampering.</li></ul> <p>The following other safety situations should also be forwarded:</p> <ul style="list-style-type: none"><li>• Drug-drug or drug-food interactions</li><li>• Suspected transmission of an infectious agent</li><li>• Occupational exposure (as a result of one's professional or non-professional occupation).</li></ul>

## **Annex 3: Revision history**

- Guidance scope changed from AE/PC collection from pharmaceutical company-sponsored websites in the June 2011 first edition of the guidance to digital media in this, the second edition.
- Guidance on non-company websites added.
- Guidance title changed from ‘Guidance notes on the management of adverse events and product complaints from pharmaceutical company sponsored websites’ to ‘Guidance notes on the management of adverse events and product complaints from digital media’ to reflect expanded scope.
- Definitions and legal framework updated to be consistent with amended regulation 1235/2010, amended directive 2010/84/EU and Good Pharmacovigilance Practice modules.
- Labels for the 3 types of social media activity updated from ‘listening in’, ‘giving out’ and ‘engaging with’, to ‘listening’, ‘broadcasting’ and ‘engaging’.

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