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Guidance notes on the management of safety information and product complaints from digital activities

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Contents

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1. Introduction

Digital activities contain digitised content that can be transmitted over the internet or computer networks. Examples of digital activities include, but are not limited to, software (such as mobile apps), digital images, digital videos, digital audio, webpages and websites and also include social media.

Digital activities are used by individuals and organisations as a component of overall communication with patients and customers to create or raise awareness about diseases and treatments. Pharmaceutical companies also use digital activities for corporate awareness, clinical trial enrolment, additional risk minimisation activities, patient support programmes, and treatment and prevention of diseases.

Consideration of company values, public expectation, legal and policy requirements are necessary for successful participation in the digital activities 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 activities. These obligations extend to third parties contracted by the MAH (e.g. vendors, partners, distributors etc), therefore agreements put in place with third parties should include provisions that allow the MAH to meet their obligations. The following notes provide guidance on the monitoring and management of safety information (SI) or product complaints (PC) arising from company-sponsored and non-company-sponsored digital activities. The term 'monitor' within this document refers to monitoring for SI/PC.

These guidance notes have been developed by the ABPI Pharmacovigilance Expert Community and other relevant stakeholders 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 activities.

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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.

2. Scope

These guidance notes refer to the collection and management of SI/PC from digital activities, which have been implemented for legitimate business purposes. This includes company sponsored, owned or controlled digital activities (e.g., 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 activities, including persons retained by way of contract with third parties (excluding individual personal use of digital activities).

3. Legal framework and guidance

Companies must comply with all applicable legislation. In Europe and therefore applicable to Northern Ireland (NI) only, two pieces of legislation underpin PV expectations: Regulation (EC) 726/2004 (as amended by Regulation 1235/2010) and Directive 2001/83/EC (as amended by Directive 2010/84/EU)[1]. Operational aspects, including the Commission Implementing Regulation 520/2012, are detailed in the associated GVP guidance[2].

For Great Britain (GB), which left the EU in 2020, the Human Medicines (Amendment etc.) (EU Exit) Regulations 2020[3] apply. Operational aspects are detailed in the associated Exceptions and modifications to the EU guidance on good pharmacovigilance practices that apply to UK marketing authorisation holders and the licensing authority[4].

GVP Module VI states[5]:

Marketing authorisation holders should regularly screen the internet or digital media[6] under their management or responsibility, for potential reports of suspected adverse reactions. With respect to this, a digital medium is considered to be company sponsored if it is owned, paid for and/or controlled by the marketing authorisation holder[7]. The frequency of the screening should allow for potential valid individual case safety reports (ICSRs) to be submitted to the competent authorities within the appropriate regulatory submission time frames 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 activity, the report should be assessed to determine whether it qualifies for submission as ICSR.

Unsolicited cases of suspected adverse reactions from the internet or digital activities should be handled as spontaneous reports. The same submission time frames as for spontaneous reports should be applied.

In relation to cases from the internet or digital activities, the identifiability of the reporter refers to the possibility of verification of the existence of a real person based on the information available (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.

Council for International Organization of Medical Sciences (CIOMS)

Section IId (p.55) of Current challenges in pharmacovigilance: pragmatic approaches, (report of CIOMS Working Group V) states[8]:

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[9] sets out requirements for promotion of medicines to health care professionals for prescribing. It also covers relationships with them, healthcare organisations and others. There are detailed training requirements in the Code including training on pharmacovigilance.

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[10].

There is further guidance on the Key Principles for Use of Social Media for the Purpose of Signal Detection or Validation in the WP1 publication April 2019: the use of social media in pharmacovigilance - https://doi.org/10.1007/s40264-019-00811-8

4. Digital activities

Types of activities in the digital environment can be varied and numerous. However, the use of social media is increasingly common. Social media activities by companies fall into three broad categories which have varying degrees of complexity, associated issues and requirements. Please note that reporter identity (e.g. 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.

In other words, social media listening may be described as a process of learning from public conversations, blog entries, virtual communities (e.g. patient or healthcare provider support communities), pictorial media accompanied by text e.g. x-rays, photographs of medical conditions, audio video, etc.

Social media listening 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 (e.g. 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 may 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' on non-company sponsored sites, it is recommended that the relevant pages of the site should be monitored for SI/PC for the period of the listening activity only. Whenever possible, the PV team should be able to influence the methods to be used for social media listening; i.e. automated vs manual. For example, automated screening of unfiltered bulk data for SI is not always advisable as these can often produce a vast number of false hits. Such automated technologies can also miss reportable SI/PCs due to incomplete search criteria or because a reportable context cannot be screened in an automated fashion. Automated tools are often more useful on data that has already been filtered using keywords, but the outputs still require human review to determine if they contain reportable safety information. Keywords used to filter the data should be reviewed on a regular basis and updated to ensure an appropriate level of sensitivity and precision is maintained.

4.2. Broadcasting

Digital activities may allow companies to initiate one-way communication to share messages/information with the public, where interactive dialogue (or other modes of interaction i.e. uploading content) is not permitted or practical.

This may include company sponsored content that is accessible from third party websites (e.g. MAH contracts with patient organisation to have sponsored content on their site). This type of activity should only allow one-way communication of information (i.e. from the company to the public) and it is important to ensure the site does not allow interactive dialogue or the creation/uploading of user-generated content. The site should also be checked to ensure that dialogue facilities do not exist (i.e. 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 (e.g. 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. This can also apply to engaging activities, please see also section 4.3. It is also important to document how SI/PC will be managed, see Section 5. It is recommended to link all "Contact us" to one central point e.g. the main company page.

4.3. Engaging

Engaging, exchanging and participating in interactive communication with the public, including bloggers, influencers and celebrities contracted by the company, is another important activity.

This action is performed in company-sponsored and non-company-sponsored digital activities. 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. If a MAH engages with (and pays) a social media influencer to promote an activity (e.g. vaccination awareness), the MAH will have to determine and stablish in a contract if the social media influencer and not the MAH will monitor for SI and the time period the SI will be monitored in the sponsored post. During engagement activity on a non-company-sponsored digital activity, the company should be transparent and declare its presence.

For users to join a company-sponsored digital activity, 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 SI/PC. It should also be made clear that personal information may be processed on internal company databases and sent to regulators (see also section 5.3).

Companies sponsoring 'interactive' digital sites 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 monitoring on every working day for the duration of the project should be considered.

Companies may wish to use online feedback surveys for multiple business purposes, and it is recommended that data collected from such activities should be monitored for SI/PC.

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

4.4. Special considerations

4.4.1. Mobile Applications (apps)

The development and publishing of mobile apps is now commonplace in the pharmaceutical industry. Many of these apps are aimed directly at HCP or patient users of company medicines. As a result, they represent a potentially significant source of safety information.

Consideration should be given to how a user of a mobile app can report SI to the company, either through functionality within the app itself or by providing contact details. If users are able to report SI proactively through the app, then a Validated Safety System needs to be in place.

In addition, careful consideration must be given to the primary purposes of the app and whether data within the app would constitute reportable safety information. For example:

- An app designed to help a patient monitor their disease symptoms whilst on a medication. If a patient enters that they have experienced a particular symptom, does the company have the ability to see/monitor this and therefore become aware of an adverse event.
- An app designed to help a patient track their medication usage to support with adherence. Could this data be analyzed to detect dose omissions, overdoses, off-label use etc.

The MAH should consider whether this classifies as listening, broadcasting or engagement and should conduct PV activities accordingly.

Underpinning the above scenarios is a question around data storage and subsequent access to that data. Understanding these technical functionalities is key for implementing the appropriate pharmacovigilance processes.

- Does the app just store data locally on the user's phone and is inaccessible to the company? In this scenario consideration should be given to encourage patients to report SI/PCs to HCPs, MAH (via other appropriate means) or the MHRA.
- Does the app store patient data in the cloud that could be accessed by pharmaceutical company staff (even if in an anonymised format)? In this scenario the usual company PV obligations would apply.

The final consideration is whether the app itself could be classified as a medical device. Although not the focus of this guidance document, apps that are classified as a medical device will have additional vigilance requirements. MHRA guidance on this topic can be found online at https://www.gov.uk/government/publications/medical-devices-software-applications-apps

Any health app that is available as part of a manufacturer-funded homecare service or Patient Support Programme (PSP) being run within the NHS in England (but not other parts of the UK) should be approved by NHS Digital through the Digital Assessment Portal[11] , prior to promoting the homecare service or PSP. This will ensure that the app meets NHS standards for safety and security.

4.4.1.1. Wearable devices

Wearable devices are smart electronic tools that can be worn as accessories (e.g. smart watches).

They incorporate powerful sensor and microprocessor technologies that can collect and deliver information on the wearer and their surroundings. Wearable devices are often used for tracking data related to health and fitness, vital signs or location. By themselves wearable devices are not a type of digital activity, but they are often linked to digital activities such as mobile device applications where data from the devices is received, analysed, visualised and shared. Anomalous fitness data would not normally be considered as safety information without confirmation and interpretation from a health care professional.

In certain scenarios, wearable devices together with mobile device applications may generate SI. In studies utilising wearable devices to measure outcomes and endpoints, data generated from the device may prompt the wearer for further information in the mobile device application the device is linked to. It is these prompts for additional user generated content that may potentially result in reports of SI. An example is a device containing accelerometers that can detect falls; detection of a fall may result in prompts asking the patient to enter further information into the mobile app the device is linked to, such as information on any injuries incurred and the outcome. It would be important to understand if/how often this information is transmitted to the MAH so that appropriate monitoring measures can be put in place to detect potential safety reports. Automated alerts, where available are beneficial in informing both the HCP and/or the MAH of potential safety reports, making the process of receiving and monitoring reports more efficient/manageable.

4.4.2. Artificial Intelligence (AI)

Artificial intelligence (AI) can be defined as the simulation of human intelligence by computer systems.

This includes the simulation of processes such as learning (the acquisition of information and rules for using the information), reasoning (using rules to reach approximate or definite conclusions) and self-correction. Tools that are underpinned by AI may be built into digital activities such as mobile device applications or websites.

With the exponential growth in technology, AI being developed and at the disposal of enterprises has increased. The use of AI is evolving rapidly and thus the considerations for pharmacovigilance can be challenging with novel tools being utilised.

In general, before being able to assess the impact of a tool utilising AI, it is important to first understand the basics of how the tool meets its objective, how data is processed and stored in doing so. For example, chat bots are tools that are driven by artificial intelligence. Such tools allow users to enter free text questions, these questions are then processed and understood by chat bot, so that a response or relevant existing content can be provided to the user. To achieve this objective, it may be necessary to store the entered text in order to run programmed operations on it. Such data may also be stored to assess and improve the tool. Data that is stored by the company or contracted third party would have to be monitored for potential AEs.

An important consideration that can have significant impact is the format of the data. AI that relies on visual input may need to store recordings; these recordings may also have an audio component. Depending on the use of the tool, there may be a high chance that the audio recordings could potentially contain safety information. An example is AI used to monitor patient compliance with dosing regimen in indications such as Alzheimer's disease or schizophrenia. In such instances it is important to understand where recordings are transmitted and stored (company servers vs patient mobile device only) as timelines for reporting valid safety reports start from when the company is in receipt of the report.

The MAH should consider whether this classifies as listening, broadcasting or engagement and should conduct PV activities accordingly.

5. General points for consideration

5.1. Project management and oversight

Consultation within the company is strongly recommended prior to the initiation of a digital activity project. Relevant groups include pharmacovigilance, legal, data protection, compliance, medical information, corporate communications and market research.

The Qualified Person for Pharmacovigilance (QPPV) should have oversight of all projects that have potential to generate safety information. Consideration of inclusion of the project in the Pharmacovigilance System Master Files (PSMF) should be made based on whether the digital activity is considered a main source of safety information.

It is recommended that each digital activity project has a project owner responsible for training and oversight of any activities including those of engaged third parties. In addition, for company-sponsored digital activities 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 activities platforms and that the online evolution of the activity (or its termination) is reviewed.

It is recommended that each digital activity 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 spokes person
- project length
- SI/PC monitoring plan, coverage, resource impact, if there will be free text options and how these will be monitored
- SI/PC reconciliation and quality control
- review schedule
- training provided and when refresher training will be due
- vendor contract and contacts etc
- data storage and access (server vs Mobile devices)
- exit strategy

When company staff or third-party vendors change in the project, it is important to re-evaluate the project plan to assess further needs to ensure compliance with applicable legislation and guidelines.

5.2. Declaration of company involvement and responsibilities

The company's involvement in a digital activity must be transparent to users. If the activity 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 digital activity (if known) and how it intends to screen and use any user-generated content.

It is advisable that company-sponsored digital activities provide a mechanism for the user to report an SI/PC to the company e.g. providing online reporting forms or contact details for direct communication (e.g. phone numbers, email address)[12]. For digital activities that are considered to be promotional then the content must adhere to the requirements of the ABPI Code of Practice, including links to the MHRA Yellow Card scheme (Clause 4.9).

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 digital activity, it is recommended that the contract describes the responsibilities of each party (especially regarding PV obligations) and gives rights for the MAH to audit the vendor.

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 SI/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 SI/PC information in order to gain more information. Please consider the General Data Protection Regulation (GDPR)[13] approved by the EU Parliament on 27th April 2016 and enforced on 25th May 2018, and the PIPA guidance notes on UK data protection in post-marketing pharmacovigilance[14].

5.4. Third Party Engagement

Third party vendors may be involved in digital activity projects.

The scope of activities for which a third party vendor may be engaged is wide and may vary from content development to monitoring for SIs/PCs. Whatever the level of engagement of the third party, it is recommended that the contract delineates the responsibilities of each party especially regarding PV obligations. Consideration to the following points should be made:

- Pharmacovigilance training (including refresher training)
- Retention of training records
- Collection and reporting of SI/PCs and other safety information
- Timeframes for reporting
- Responsibilities for follow-up activities
- Reconciliation activities
- Record retention
- Audit rights
- List of contacts at both parties
- Termination activities

6. Training

MAHs should ensure that all staff and third party vendors involved in digital activity projects are appropriately trained for performing pharmacovigilance related activities. Individuals responsible for monitoring the digital activities for SI/PC should receive specific training (and periodic refresher training for ongoing projects) on the identification of SI/PC, see Annex 2. 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 SI and PCs from company-sponsored digital activities

Company-sponsored digital activities 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 SI/PCs 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 digital activities, particularly in relation to safety of their medicines.

MAHs conducting 'listening', 'broadcasting' and 'engaging' activities on company-sponsored digital activities have an obligation to collect and follow-up on SI/PC associated with their products. Details of all SI/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 SI 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
- an adverse event
- an identifiable reporter

In relation to cases from digital activities specifically, the identifiability of the reporter refers to the possibility of verification of the existence of a real person based on the information available; 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.

All SI/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 of the relevant section containing the SI only is saved and used as the source documentation.

Automation may be used to screen company sponsored digital activities for SI/PC (use of a search string, algorithms, dictionaries, ontologies and natural language processing to narrow down the data to entries likely to contain safety information). Precautionary measures should be taken when setting up automation to ensure that these tools are sensitive enough to identify all SI/PC and precise enough to justify their use and the efficiencies they may bring. Companies should consider pilot periods whereby automated screening is run alongside manual screening to allow adjustments to be made to the tools before they become fully operational. Periodic comparison of results for automated screening against results from manual screening should also be considered to ensure ongoing correct functioning of the tools. Attempts should be made to obtain follow-up information relating to SI/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 SI and PCs from non-company- sponsored digital activities

If a company (or contracted third party) chooses to participate in activities in non-company sponsored digital activities and identifies a SI/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.

Software applications that companies own or control (apps) e.g. for smart phones and tablet computers, may be made available on an independent distribution platform (e.g. App Store). An app user (e.g. a patient or healthcare professional) may post comments on these independent distribution platforms. The MAH would not routinely be required to monitor or review comments posted on these app distribution platforms which are considered non-company sponsored digital activities. However, should the MAH periodically review these comments for other purposes, any SI/PC identified should be collected and reported appropriately. As there is no legal requirement to monitor non-company sponsored digital activities, Day 0 is the day the MAH first becomes aware of the SI/PCs. Content generated via the app itself and accessible to the company is under the management and responsibility of the MAH.

MAHs may become aware of a SI/PC on non-company-sponsored public portals or micro-blogging digital activities 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 (e.g. SI/PC reporter) to contact the company via the company website, email or phone to provide further SI/PC information.

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3. The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020
4. Exceptions and modifications to the EU guidance on good pharmacovigilance practices that apply to UK marketing authorisation holders and the licensing authority
5. European Medicines Agency. Good pharmacovigilance practices Module VI (Rev 2), Section VI.B.1.1.4. Available at: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-good-pharmacovigilance-practices-gvp-module-vi-collection-management-submission-reports_en.pdf
6. Although not exhaustive, the following list should be considered as digital activities: website, web page, blog, vlog, social network, internet forum, chat room, health portal.
7. 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.
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Annex 1: Abbreviations

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

Annex 2: Definitions

The definitions are taken from the Good vigilance practice (GVP) guidance, or where appropriate they have been aligned with the GVP.

Term	Meaning
Adverse Drug Reaction / Adverse Reaction	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. 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.
Adverse Event	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.
Company-Sponsored Digital Activity	A digital activity 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. A company may sponsor a 'page' on a website/platform that they do not own (e.g. a social media or micro-blogging sites). If the company has control over the content of a sponsored page, it is considered company-sponsored.
Non-Company-Sponsored Digital Activity	A digital activity is considered to be non-company-sponsored if is not owned, paid for or controlled by the company. For such a digital activity, there must be no possibility that the pharmaceutical company has been able to exert any influence or control the final content. 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 digital activity.

Term	Meaning
Product Complaint (PC)	Product complaints are a customer's written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a product after it is released for distribution. This includes when the ability to use the product safely is impacted, deficiencies in labelling information and use errors for device or combination products due to ergonomic design elements of the product are also product complaints.
Safety information (SI)	▪ Adverse event ▪ 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) ▪ Exposure to a drug during breast-feeding/lactation ▪ Overdose (whether intentional, accidental or prescribed) ▪ Drug abuse or misuse ▪ Medication errors (including dispensing errors, accidental exposure, maladministration, etc.) ▪ 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. ▪ Reports of lack of therapeutic effect or other product complaints associated with an adverse event, including suspected use of counterfeit medicine/ tampering. ▪ Drug-drug or drug-food interactions ▪ Suspected transmission of an infectious agent ▪ Occupational exposure (as a result of one's professional or non-professional occupation).

Annex 3: Revision history

Version 2.0 update

- Guidance scope changed from AE/PC collection from pharmaceutical company-sponsored websites in the June 2011 first edition of the guidance to digital activities 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 activities' 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'.

Version 3.0 update

- AE term replaced by a broader term of safety information (SI) and definition of SI provided
- Update to PC definition.
- Digital media term changed to digital activities
- Update to GVP module VI
- Section 4 expanded to include further digital activities
- Reference to the publication on social media use in signal detection
- Further details added to section 5.1 points for consideration
- Section 5.4 -Third party engagement added
- Section 7 updated to include further details on digital activities

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