

Guidance notes for patient safety and pharmacovigilance in *patient support programmes*

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1 Introduction

Many pharmaceutical companies run Patient Support Programmes (PSPs) to help patients and/or healthcare professionals better manage disease and optimise treatment. When conducting PSPs safety data may be generated relating to the use of a medicinal product. For the purposes of these guidance notes, the word ‘patient’ refers to any user of the medication. It is imperative that patient safety is a priority in such programmes and that the marketing authorisation holder (MAH) is able to meet ethical, legal and regulatory obligations including pharmacovigilance (PV) requirements.

A PSP is an organised data collection system (ODCS) where a marketing authorisation holder receives and collects information relating to the use of its medicinal products. Examples are post-authorisation patient support and disease management programmes, surveys of patients and healthcare providers, information gathering on patient compliance, or compensation/reimbursement schemes.¹

As PSPs are a source of safety data, they fall within the scope of an MAH’s pharmacovigilance system; however, many instances of non-compliance have been identified in regulatory authority inspections. Regulatory authority inspectors often request evidence to support good governance and oversight of such programmes, e.g. that MAHs and any MAH-contracted third parties involved in the programmes have well documented processes in place, particularly for PV and evidence of PV training. As such, the MAH PV departments must be aware of PSPs and involved appropriately, e.g. proof of concept and contractual review.

These guidance notes were developed by the ABPI Pharmacovigilance Expert Network (PEN) based on current legislative requirements and recent inspection findings and shared with the Medicines and Healthcare products Regulatory Agency (MHRA). The guidance notes were reviewed by relevant stakeholders.

These guidance notes are intended to help departments in companies initiating and conducting PSPs to appropriately consider and address PV obligations and regulatory authority expectations. They also provide general considerations for design, initiation, ongoing management and closure of PSPs. These guidance notes are intended for use by all functional areas involved in PSPs, including marketing departments.

It is up to each MAH to decide, in the context of their circumstances, how to apply these guidance notes. Other requirements may be relevant and must be complied with, such as the ABPI Code of Practice for the Pharmaceutical Industry.

It is critical that PV departments are involved from the point of concept of any PSPs initiated by any functional area so that PV and regulatory obligations can be met.

¹ Guideline on good pharmacovigilance practices (GVP), Module VI – Management and reporting of adverse reactions to medicinal products (Rev 2) (EMA, July 2017)

2 Scope

It should be noted that guidance in this document relates only to PV aspects of PSPs.

This guidance applies to PSPs with authorised medicines only. All customer engagement programmes should be considered to determine if they have the potential to generate safety data.

This guidance includes specific PV recommendation for joint homecare delivery and PSPs (see Annex 3). NHS home delivery is not covered by this guidance.

Interventional clinical trials, non-interventional studies (with protocols), compassionate use or named patient use, post-authorisation safety and efficacy studies are excluded from this guidance and should be managed in accordance with the relevant requirements.

There is a separate ABPI PEN guidance notes document that should be consulted for market research activities.²

3 Types of Patient Support Programme

Examples of PSPs (for definition, see Annex 2) that aim to help patients, either directly or via healthcare professionals (HCPs) to better manage disease outcome, understand their conditions and/or provide advice on managing disease, are:

- compliance/adherence programmes where consenting patients on a medication are contacted to see how they are managing with their medication;
- call centres where patients or patient carers can contact the MAH to obtain further information on medication or a particular disease area as part of a structured programme (this excludes routine 'medical information' services);
- 'nurse educator' programmes where nurses (either employed directly by an MAH or through a third party) interact directly with patients to provide education or disease awareness, to help them properly administer medications and/or manage their disease.

Guidance from the PV team should be sought to determine whether or not other activities providing a service or arranging financial assistance for patients are also PSPs.

Examples include:

- patient access schemes (such as reimbursement schemes);
- home delivery/homecare programmes (further details/guidance can be found in Appendix 3).

According to guidance in GVP Module VI, PSPs are included in the definition of organised data collection schemes (ODCS) and any safety data received from PSPs should be handled as solicited reports.

² ABPI BHBIA Guidance notes on the collection of adverse events and product complaints from market research programmes (ABPI, BHBIA, April 2013)

4 Elements of PSP design which may impact PV processes

A brief summary of specific PV requirements for PSPs can be found below to illustrate aspects which must be considered to ensure compliance:

- The PV function must be involved from the initial design stage to avoid generation of inappropriate data and ensure the project is compliant with appropriate regulations.
- PSPs are sources of Safety Information and they must be included in the PV system master file (PSMF) to support EU QPPV oversight.³

PSPs may involve direct contact between the MAH (or a third party) and the patient by phone, mail, email or text messaging and they may or may not include involvement from HCPs. Interactions may also be face to face.

Digital media⁴ may be a part of a PSP, and Safety Information – including adverse event (AE) reports – may be received via MAH sponsored or controlled websites, where free text or other functionalities allow the MAH to solicit information from a user.

Companies should consider internal reporting timelines to ensure compliance with legislative requirements. For simplicity, AEs, product quality complaints (PQCs) and special situations that require reporting to the MAH will be collectively referred to as 'Safety Information' in these guidance notes. Staff involved in monitoring or using digital media must be trained in the identification and collection of Safety Information and the process for forwarding reports to the PV department.

If a third party is involved, the contract should include wording to describe all PV responsibilities, including reporting of AEs, PQCs and special situations that require reporting to the relevant MAH contacts (see Annex 2) within defined timelines.

It is recommended to have a single point of accountability to take overall responsibility for each PSP and gain the necessary cross-functional co-operation and endorsement. The person identified as the single point of accountability must be within the commissioning MAH if a third party will be running the PSP. The single point of accountability has responsibility for ensuring compliance with all PSP-related requirements, not just PV requirements. The person is quite often the programme owner and must maintain close collaboration with the PV department to ensure all PV aspects are appropriately addressed. The single point of accountability should refer to the relevant experts within the MAH for guidance on other compliance areas.

The single point of accountability must ensure that:

1. procedures for identifying, collecting and following up Safety Information are established so that appropriate signal detection activities and ongoing safety assessment of the medicines can be performed by the MAH's PV department;
2. adequate training on Safety Information identification and collection procedures and documentation of the training is performed for all internal and third parties involved in the PSP. The PV training must meet the requirements of the MAH's PV department. The initial PV training must be completed prior to initiation of the PSP, or before internal or third-party staff actively engage in an ongoing programme, and periodically refreshed thereafter.

³ Guideline on good pharmacovigilance practices (GVP) , Module II – Pharmacovigilance system master file (Rev 2) (EMA, March 2017)

⁴ ABPI Guidance notes on the management of adverse events and product complaints from digital media (ABPI, April 2013)

5 Documenting PSPs

Clear documentation should be maintained for all PSPs. This type of information is often requested during PV inspections and audits, and should provide evidence that safety requirements have been considered and actioned.

The documentation should outline how PSP objectives and all compliance requirements will be achieved and define the responsibilities of each stakeholder group applicable to the PSP. PSPs should be developed with input from

PV and the development must be fully documented and approved across the involved functional departments prior to the commencement of the PSP. Documentation is recommended for all the following stages:



To facilitate a robust oversight mechanism for the EU QPPV and any relevant key stakeholders, all MAHs should ensure a system is in place for recording details of all PSPs, ideally in an access-controlled and validated central repository.

5.1 Planning

The objective of the PSP should be stated clearly. This should include evaluation of the benefit for patients. This could be assessed by the MAH's internal governance processes. Approval to proceed needs to be documented.

5.1.1 Governance, awareness and policy

In order to ensure PV is involved from the initial design stage of and changes to these types of activity, it is recommended that all MAHs have policies/standard operating procedures (SOPs) that cover PSPs. These policies/SOPs should be disseminated to all potential staff who may initiate, conduct or be involved in a PSP including, but not limited to, marketing, medical affairs, market access and pharmacovigilance personnel.

The policies/SOPs should reinforce PV requirements; and include roles and responsibilities, accountability and the required controls to facilitate consistency and adherence.

There should be a clearly defined escalation procedure in case of any disagreement, non-compliance or challenges (internal and external) experienced in the PSP.

5.2 Set-up and implementation

Distinct documented processes should exist within an MAH to ensure the organisation can demonstrate appropriate due diligence.

Careful and early consideration of the design will help to optimise the management of the Safety Information with minimal resource impact, e.g. review of call scripts by PV staff to avoid inappropriate solicitation of Safety Information.

5.2.1 PSP design

When designing the PSP it is recommended to involve PV and key functional areas to ensure appropriate PV activities are included at the design stage. It is important to consider all factors and barriers that may affect how a PSP will progress. For example, the design of the technical database structure and the specific questions used in an electronic patient 'wellness tracker' could be influenced by PV in such a way as to minimise the potential for irrelevant Safety Information to be collected.

5.2.2 PSP PV requirements

Methodology will vary according to the type of PSP; consideration of the following should be given, as appropriate:

- a) **Operational details** – Suitably PV trained and qualified individuals on the programme, and operational logistics (e.g. home visits, telephone call service, online help, timings, service provision).
- b) **Handling participant interaction** – The level and frequency of interactions, ensuring a defined process for handling information received via face-to-face or telephone contact, or any other form of communication.
- c) **Patient registration** – Patient/participant consent for participation in the programme to be obtained before the patient/participant is included in the PSP. The capture of consent may also include wording relating to permission for the MAH's PV department to request follow-up information and a description of how Safety Information will be processed. Alternatively, consent for follow-up can be requested at the time of Safety Information reporting/capture.
- d) **Safety data handling** – A description of the responsibilities for detection and onward routing of Safety Information reports to the PV department should be given, as well as a description of the responsibilities for the routing of PQCs.

Any relevant performance measures (e.g. on compliance reporting, over-/under-reporting) and the management of any data capture should also be documented. Methods for follow-up with the reporter/participant for further AE information should be defined.

A method needs to be implemented to ensure that all relevant Safety Information has been reported during the PSP and received by the PV team. In practice this is usually performed through reconciliation activities.

It is recommended that a mechanism for reconciliation and source data verification is described in the contract with details of Safety Information handling.

- e) **Patient materials** – Materials intended for use in the PSP should be included in the documentation for the PSP. These materials, as appropriate, should be reviewed and approved by the MAH's PV department prior to use.

5.2.3 Data protection

PSPs involve data capture of personal data and appropriate data protection must be ensured. You should consult your local legal contact with regard to inclusion of suitable confidentiality and data protection provisions and statements⁵. Consideration needs to be given to documentation of patient consent to allow data to be shared with the MAH. Consent, if required for the programme, needs to cover transfer of required data between all relevant groups involved in the PSP. The required data to be shared must be specified before commencing a PSP.

5.2.4 Pharmacovigilance training

Companies have an obligation to ensure staff involved in a PSP receive PV training to support recognition of Safety Information and ensure appropriate and timely forwarding of this to the MAH. All staff involved in a PSP should receive their PV training prior to initiation of the PSP (or prior to their involvement in the PSP if they are not involved at the initiation), periodically throughout the duration of the PSP and whenever important changes to the conduct of the PSP or the reporting of Safety Information occurs. This includes PSPs involving the use of call/booking centre staff. Companies should also evaluate if other staff should be trained, such as those involved in personal delivery of medication. Various forms of training include, but are not limited to, specific PV training, use of information card or instruction on MAH contact details for reporting. If appropriate, it might be necessary to train on additional risk minimisation measures/materials (RMMs).

When a PSP is outsourced to a third party, the MAH should ensure it has systems in place to monitor compliance of the outsourced activity. Detection of both under-reporting (extrapolated within the context of expected reporting rates and associated key performance indicators) and

5 ABPI Guidance on UK data protection in post-marketing pharmacovigilance (ABPI, February 2013)

over-reporting of Safety Information carry equal importance for overall patient safety and compliance. Therefore, it is important for the MAH to have oversight of all third-party personnel involved and to ensure that all training is documented; including who received it, who provided it, what was provided, and the training date. Third-party staff involved in a PSP may receive additional training, such as product training, as appropriate. Inspectors may request these documents during a regulatory inspection.

5.3 Reporting: patient safety and handling AE data

The MAH must ensure it complies at all times with both corporate policies and applicable legislation which place strict timelines for PV requirements in order to ensure patient safety.

All Safety Information (AEs, POCs and special situations that require reporting to the MAH – (see Annex 2) from PSPs should be collected. Safety Information collection is a legislative requirement when conducting PSPs, as specified in the EU legislation governing PV for pharmaceutical companies and the implementing guidelines for this legislation⁶.

All Safety Information reports must be forwarded to the MAH's point of intake (e.g. local PV department) within defined timelines. Reporting timelines should be documented in the contract with any third parties involved. It is important to note for outsourced programmes that the date of awareness (Day 0) which drives any expedited reporting of AEs, is the date the third party becomes aware, not the date the report is passed to the MAH. This should be meticulously defined within the provisions of any contract or PV process definition as applicable.

The MAH should ensure there is a mechanism in place for the staff and providers to receive important updates on the product safety profile (e.g. new identified or potential risks added to a risk management plan (RMP) or any safety updates that have invoked a change to the summary of medicinal product characteristics (SmPC) including changes in the benefit-risk profile of the product concerned) where it is relevant to the programme they are conducting and the safety of any patients involved in the programme.

A process of self-monitoring of programmes needs to be implemented, e.g. internal quality assurance process/ peer-reviews/ data checks to ensure all information recorded does not contain any 'missed' Safety Information.

5.4 Maintenance and issue escalation

As stated above, it is recommended that the MAH has provisions and clear procedures to define continuous compliance monitoring and subsequent ongoing improvement mechanisms as agreed in the contract or safety data exchange agreement.

Persistent compliance deficiencies should be considered for escalation to relevant governance/decision boards, as appropriate.

5.5 Closure

When a PSP is terminated, the MAH needs to be able to demonstrate that all Safety Information has been appropriately forwarded to and captured by the PV department. It should be borne in mind that Safety Information relating to the PSP could be received after termination of the PSP. The MAH needs to ensure there are processes in place to address this.

It is good practice to issue a PSP closure notification once it is confirmed that all documentation, appropriate sharing of Safety Information and periodic (usually monthly) checks are complete. It is important to make sure that all departments involved in the PSP are notified of the closure.

Where PSPs are outsourced, the contract set up at the initiation of the PSP should include the requirements of any third party for PSP closure. This should include the length of time that periodic checks will continue (since the third party could continue to receive reports after termination of the PSP). The length of time that periodic checks should continue for will depend on the nature of the PSP.

Change of third party, if the PSP is outsourced, should be considered as closure of the PSP for the current third party and initiation for the new third party, and all the required actions should be completed.

6 Outsourcing

If a third party is identified to run the PSP on behalf of the MAH, it should undergo detailed assessment (qualification, selection and/or audits) by the MAH to determine whether it has the capabilities and/or capacity, processes and personnel to run the programme. The MAH should ensure patient safety is a priority; that all PV requirements can be met, and that third-party staff are adequately trained prior to the start of the PSP and throughout its duration.

Following assessment, a detailed contract should be created, to be signed and agreed between both parties before any activities begin. The contract should describe all obligations under the scope of the PSP including PV training, reconciliation, compliance monitoring, data protection, confidentiality provisions and back-up or continuity plans for all systems employed.

Safety data exchange provisions should be defined in the contract between the MAH and the third party. It is important to continuously involve the PV department in developing and finalising language for these contractual arrangements, which should include:

- definitions;
- the process for forwarding Safety Information in defined timelines;
- an agreed reconciliation process between the MAH and the third party to ensure that all identified AEs have been forwarded and received by the MAH;
- an agreed quality check process (e.g. source data verification) between the MAH and the third party to ensure all Safety Information has been identified by the third party;
- provision for the MAH's right to audit the third party;
- the requirement for PV training of all third-party personnel before they start working on the PSP and periodically thereafter throughout the conduct of the PSP;
- a method for making the MAH aware of key staff changes during the PSP;
- documentation of a clear communication process with contacts for both parties including the process for escalation of any issues;
- details of/ guidance on required actions on closure of the PSP and/or changes to third-party provisions. This should include confirmation that all Safety Information has been appropriately exchanged prior to closure of the PSP or change of third-party provider.

Annex 1: Abbreviations

ABPI	The Association of the British Pharmaceutical Industry
ADR	Adverse Drug Reaction
AE	Adverse Event
EU	European Union
GVP	Good Pharmacovigilance Practice
HCP	Healthcare Professional
ICH	International Conference on Harmonisation
MAH	Marketing Authorisation Holder
MHRA	Medicines and Healthcare products Regulatory Agency
ODCS	Organised Data Collection Scheme
PEN	ABPI Pharmacovigilance Expert Network
PQC	Product Quality Complaint
PSMF	Pharmacovigilance System Master File
PSP	Patient Support Programme
PSUR	Periodic Safety Update Report
PV	Pharmacovigilance
QPPV	Qualified Person for Pharmacovigilance
RMM	Risk Minimisation Measures
RMP	Risk Management Plan
SmPC	Summary of medicinal Product Characteristics
SOP	Standard Operating Procedure

Annex 2: Definitions

<p>Adverse Event</p>	<p>Any untoward medical occurrence in a patient or clinical-trial subject administered a medicinal product, which does not necessarily have to have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign (e.g. 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>
<p>Adverse Drug Reaction</p>	<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 error.</p>
<p>Homecare Service (referred to as Homecare)</p>	<p>A service that delivers ongoing medicine supplies and, where necessary, associated care, initiated by the hospital prescriber, direct to the patient's home with their consent.</p> <p>The purpose of the homecare medicines service is to improve patient care and choice of their clinical treatment.</p> <p>Definition from Royal Pharmaceutical Society Handbook for Homecare Services in England May 2014.⁷</p>
<p>Market Research</p>	<p>A market research programme refers to the systematic collection, recording and analysis by an MAH of data and findings about its medicinal products relevant for marketing and business development.</p> <p>Guidance notes on the collection of adverse events and product complaints from market research programmes.⁸</p> <p>Guideline on good pharmacovigilance practices (GVP), Module VI – Management and reporting of adverse reactions to medicinal products (Rev 2).⁹</p>
<p>Organised Data Collection Scheme</p>	<p>An ODCS is any activity undertaken by an organisation (including pharmaceutical companies) which may involve contact with patients/ caregivers and/or HCPs, with the potential of generating and collecting data relating to the use of a medicinal product. This includes clinical trials, post-authorisation named patient use programmes, other patient support and disease management programmes, surveys of patients or healthcare providers, or information gathering on efficacy or patient compliance, consistent with the definition in ICH E2D.</p>
<p>Product Quality Complaint</p>	<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>

⁷ Definition from Royal Pharmaceutical Society Handbook for Homecare Services in England May 2014. (RPS, 2014)

⁸ Guidance notes on the collection of adverse events and product complaints from market research programmes (ABPI, 2013)

⁹ Guideline on good pharmacovigilance practices (GVP), Module VI – Management and reporting of adverse reactions to medicinal products (Rev 2) (EMA, July 2017)

<p>Patient Support Programme</p>	<p>An organised system where a marketing authorisation holder receives and collects information relating to the use of its medicinal products. Patient Support Programmes include post-authorisation patient support and disease management programmes, surveys of patients and healthcare providers, information gathering on patient compliance, or compensation/reimbursement schemes. Guideline on good pharmacovigilance practices (GVP), Module VI – Management and reporting of adverse reactions to medicinal products (Rev 2).¹⁰</p>
<p>Risk Management Plan</p>	<p>A detailed description of the risk management system.</p>
<p>Risk Management System</p>	<p>A set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to a medicinal product, including the assessment of the effectiveness of those interventions.</p>
<p>Risk Minimisation Measure</p>	<p>An intervention intended to prevent or reduce the probability of the occurrence of an adverse reaction associated with the exposure to a medicine, or to reduce its severity should it occur. These activities may consist of routine risk minimisation (e.g. product information) or additional risk minimisation activities (e.g. healthcare professional or patient communications/educational materials).</p>
<p>Safety Information</p>	<p>Collective term in these guidance notes for Adverse Events, Product Quality Complaints and special situations that require reporting to the MAH.</p>
<p>Serious Incident</p>	<p>In broad terms, serious incidents are events in healthcare where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response. Serious incidents can extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or an organisation’s ability to deliver ongoing healthcare.</p>
<p>Special situations that require reporting to the MAH</p>	<p>All of the following situations associated with the use of a company product should be reported, whether or not there is an associated AE:</p> <ul style="list-style-type: none"> • 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 or near-misses (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. <p>The following other safety situations should also be reported:</p> <ul style="list-style-type: none"> • 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)
<p>Third party</p>	<p>Often referred to as a third-party vendor or vendor. An individual or company performing activities on behalf of someone else (usually the marketing authorisation holder (MAH) in the scenarios mentioned in these guidance notes). The MAH retains responsibility for the activities performed by the third party.</p>

¹⁰ Guideline on good pharmacovigilance practices (GVP), Module VI – Management and reporting of adverse reactions to medicinal products (Rev 2) (EMA, July 2017)

Annex 3: Homecare considerations and best practice

This annex provides further guidance on:

1. the handling of Safety Information;
2. confirmation of collection of all Safety Information.

Homecare (which may be referred to as a homecare service) is a homecare medicine delivery service that can be described as a service that delivers ongoing medicine supplies and, where necessary, associated care, initiated by the hospital prescriber, direct to the patient's home with their consent. The purpose of the homecare medicines service is to improve patient care and choice of their clinical treatment.¹¹

This guidance relates purely to PV reporting requirements when a homecare company is contracted by an MAH. Outlined below are the actions homecare companies should take to support best practice and the efficiency and accuracy of operations. It is intended to reinforce and clarify

required procedures. Broader requirements relating to safety reporting can be found within contracts. Where a homecare company is contracted directly by the NHS, this is outside the scope of this guidance.

It is acknowledged that homecare companies have a requirement to monitor Incidents and define Serious Incidents. PV data is usually classed in the category of Serious Incidents. MAHs need to be aware of the additional requirements on homecare companies. Where a homecare company is contracted to provide homecare services on behalf of an MAH, PV reporting should be to the MAH. This does not negate any requirements for the homecare company to report to the patient's clinical care team.

¹¹ Definition from Royal Pharmaceutical Society Handbook for Homecare Services in England May 2014. (RPS, 2014)

1. Safety Information

All Safety Information should be reported to the MAH within the timelines stated in their contract. This is usually one business day. The MAH should provide/validate PV training to all appropriate homecare company staff based on the specific requirements of the PSP.

The MAH and homecare company need to agree which AE reporting form/process must be used. At a minimum, the homecare company should provide:

- a patient identifier;
- details of the suspect drug/device/vaccine including batch number;
- details of the Safety Information;
- reporter details; consent must be obtained to contact the patient's HCP if necessary to request additional report information;
- date of first awareness of the Safety Information by the homecare company staff;
- the programme name/ID where multiple programmes are run by the same homecare company on behalf of the MAH.

At the time of awareness of the report, the homecare company staff must make the reporter aware that the information needs to be sent to the MAH and that the MAH may wish to follow up to obtain more information. Homecare company staff can explain that obtaining such information is an MAH's legal requirement to ensure continuous safety monitoring of medicines and devices. Since the reporter is likely to be the patient or a carer (non-healthcare professional), the homecare staff should request permission to follow up with the patient's HCP. Confirmation that permission to follow up has been requested must be provided with the report together with details of the patient's HCP contact details (if permission to follow up has been granted).

Guidance should be provided by the MAH to clarify which information needs to be captured as PQCs and, in particular, which information should be reported to both the MAH's PV and Quality teams.

2. Confirmation of collection of all Safety Information

- Acknowledgement and reconciliation processes must be in place.
- Quality checks must be in place to ensure all Safety Information has been transferred. Where there are a large number of interactions, a randomised sample for further investigation may be selected.

If a homecare company has missed any reports of AEs, PQCs or special situations that require reporting to the MAH, the missed information should be sent to the MAH immediately.

The MAH should notify the homecare company of any missed reports identified as part of the MAH's compliance monitoring. It is best practice for the homecare company to investigate any missed reports and provide details of actions taken to prevent a reoccurrence in the future.

Annex 4: Changes since previous version

- Updated in light of revised EU pharmacovigilance legislation and pharmacovigilance guidance
- Removal of AE classification as now covered in Module VI of the Good Vigilance Practice guidance
- Added Annex 1: Abbreviations
- Updated Annex 2: Definitions
- Added Annex 3: Homecare considerations and best practice

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