Guidance notes on collecting adverse events, product complaints and special reporting situations during market research

August 2018

These Guidance Notes have been developed by the ABPI Pharmacovigilance Expert Network (PEN) and the British Healthcare Business Intelligence Association (BHBIA).

Approval status

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1 INTRODUCTION

1.1 Why have we written this?

So that market research agencies and marketing authorisation holders have guidance when collecting and forwarding information about an adverse event (AE), product complaint (PC) or special reporting situation (SRS) that comes up during a market research project when the company commissioning the research is a marketing authorisation holder (please see Section 1.2 for the definition of this term).

The ABPI Pharmacovigilance Expert Network (ABPI PEN) and the British Healthcare Business Intelligence Association (BHBIA) have worked together to give you relevant information which we hope will help.

Please remember this isn't a) regulatory or legal advice or b) a comprehensive guide to how a market research agency (MRA) or marketing authorisation holder (MAH) should manage the reporting of AEs, PCs or SRSs. So, when we discuss pharmacovigilance in the context of market research, we can and may take a different position.

1.2 Who is it for?

We've written this to help all market researchers who specialise in healthcare – whether working for an MRA or an MAH:

Market research agency (MRA)	The company that the MAH (or other company) commissions to carry out the market research, plus all subcontractors, fieldworkers, analysts and interviewers that the MRA engages (in any way).
Marketing authorisation holder (MAH)	The organisation that is legally responsible for the quality, efficacy and safety of a medicine. In the context of market research, the MAH may contract with a third party who then commissions the MRA to carry out the market research. Any reference we make to an MAH includes any of these third party organisations.

1.3 What does it cover?

These Guidance Notes suggest a best practice for MRAs on collecting, forwarding and managing AEs, PCs and SRSs.

It applies to:

- the following types of market research that are connected with medicinal products in therapeutic areas authorised for human use where a company has responsibilities as a UK MAH:
  - Primary market research – a company commissions/supports and fields it in the UK (wherever the company is located). Primary data is collected directly from respondents; it is ad hoc market research generating original data to address a specific issue.
  - Syndicated market research – an MAH acquires the market research data and the MAH is responsible for reporting to the regulatory body any AEs, PCs or SRSs associated with its products. Syndicated data is collected by a MRA and shared (both the findings and the costs) with a number of clients, the data are collected independently of an individual company.
- all market research methodologies, project types and mediums including qualitative, quantitative, customer satisfaction, user experience or co-creation work carried out face to face, by telephone or online. Online market research includes digital media research, digital listening, online surveys and market research online communities. For further detail upon the definition of market research please see the BHBIA's Legal and Ethical Guidelines, section H1.

It does not apply to:

- in-licensing opportunities or when a company is not the MAH
- market research conducted outside the UK
- clinical trials

For information about adverse events, product complaints and special reporting situations in relation to medical devices, please contact the company commissioning the market research.

1.4 What is the legislation?

Pharmacovigilance is regulated by:

- Regulation (EC) 726/2004 (as amended by Regulation 1027/2012) implemented into national law by the Human Medicines Regulations 2012
- Directive 2001/83/EC (as amended by Directive 2012/26/EU)
- Commission Implementing Regulation 520/2012
- Guideline on Good Pharmacovigilance Practices Module VI – Management & Reporting of Adverse Events to Medicinal Products (Rev 2)
- ICH Harmonised Tripartite Guideline – Maintenance of the ICH Guideline on Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports (E2B) R3

Data protection is regulated by:

- EU General Data Protection Regulations 2016/679 (GDPR) as implemented into national law by the Data Protection Act (DPA) 2018.

1.5 What training is available?

An online electronic training programme (developed by the BHBIA in partnership with the ABPI PEN) is available on the BHBIA website to help all market researchers (their suppliers, subcontractors and others) recognise and collect AEs, PCs and SRSs.

We recommend you complete this if you work in:

- a pharmaceutical company and are involved in market research
- an MRA (or their subcontractor) that carries out market research on behalf of a pharmaceutical company

The BHBIA also offer an online competency test and certification process that must be renewed each year. It is recommended that all pharmaceutical companies ask representatives of MRAs (and subcontractors) to provide this proof of competency before commissioning them to work on any market research programmes.

2 DEFINITIONS

2.1 What is pharmacovigilance?

Pharmacovigilance is *'the science and activities relating to the detection, assessment, understanding and prevention of adverse effect or any other medicine related problem'*[1]

A medicinal product can only be placed on the market when the relevant regulatory authority has granted permission to the company that will sell the product (the MAH).

MAHs have a legal and regulatory obligation to monitor, collect and manage AEs, PCs and SRSs.

2.2 What is an adverse event?

An adverse event (AE) is *'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 temporarily associated with the use of a medicinal product, whether or not considered related to the medicinal product.[2]

Where it is reasonable to consider there's a causal relationship between a medicinal product and an AE (ie. that a medicinal product is contributing to causing an AE), and the response to the medicinal product is noxious and unintended, the AE is known as an '*adverse drug reaction*'.[3]

2.3 What is a product complaint?

A product complaint (PC) is any alleged failure of a product, including identity, durability, reliability, safety, efficacy or performance. It is specific to the product itself or its packaging, as opposed to its effect on the patient. For example:

- 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
- The identification of a potentially counterfeit medicine

2.4 What is a special reporting situation?[4]

The following are all special reporting situations (*SRSs*):

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[1] The European Medicines Agency website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000258.jsp&mid=WC0b01ac0580b18c76 accessed on 21 June 2018.
[2] Directive 2001/20/EC (Article 2(m))
[3] Guideline On Good Pharmacovigilance Practices (GVP) – Annex 1 – Definitions (Rev 4) EMA/876333/2011 Rev 4.
[4] Guideline on Good Pharmacovigilance Practices (GVP) – Module VI – Collection, Management and Submission of Reports of Suspected Adverse Reactions to Medicinal Products (Rev 2) – EMA 873138/2011.

- Exposure through a parent ie. drug exposure to a foetus in utero (whether the foetus is exposed because the mother took the product during pregnancy or transmission from semen following the father's exposure to the product)

- Use of a medicinal product during pregnancy or breastfeeding

- Reports of overdose, abuse, misuse

- Lack of therapeutic efficacy including suspected use of counterfeit/falsified medicines/tampering

- Medication errors (including dispensing errors, accidental exposure, maladministration etc.)

- Unapproved, or off-label use of a product ie. intentional medical use that doesn't comply with the authorised product information (including off-label use in children or the elderly)

- Withdrawal syndrome

A company may also indicate to the MRA that it considers the following to be an SRS and the MRA should make sure it understands exactly how the company defines this:

- Unexpected therapeutic benefit (the pre-existing condition improved)

Please also send the MAH any information received relating to these safety situations:

- Drug or drug-food interactions

- Suspected transmission of an infectious agent

- Occupational and environmental exposure (as a result of a professional or non-professional occupation)

3 RESPONSIBILITIES

3.1 Who must comply?

The MAH has primary responsibility for compliance with pharmacovigilance legislation and for assessing whether market research activities may generate AEs, PCs or SRSs.

However, where it engages an MRA to provide services, it usually requires (in the contract) that the MRA assists it in this by reporting AEs, PCs and SRSs to the MAH. See Annex 2 for an example of standard wording for this. Once the MRA has reported to the MAH, the MAH's pharmacovigilance department is responsible for all associated follow-up actions, if appropriate.

Remember, the MRA can only pass the contact details of the market research participant to the MAH if there is a lawful basis (under data protection legislation) for this in place. Obtaining the market research participant's consent is the most commonly used lawful basis for the transfer of personal data, but it is important to be aware that this is not the only option. Please see Annex 5 for further details of different potential lawful bases. If consent is the lawful basis for the transfer of personal data, the MRA should obtain consent for processing personal data for AE, PC and SRS reporting at the end of the interview as this is not essential to participation in the market research; the transfer of personal data for these purposes is a separate data processing operation.

If the MRA subcontracts its market research obligations to a third party (eg. a fieldwork agency), it should ensure that this subcontractor is also obliged to report AEs, PCs and SRSs, and to comply with all legal, regulatory and contractual requirements in general.

In a co-promotion or co-marketing situation, the MRA should consult with the commissioning company to determine the process for forwarding AEs, PCs and SRSs.

3.2 What must market research agencies do?

3.2.1 Before you start any fieldwork with a research participant, you must inform them of your agency's obligation to report AEs, PCs and SRSs to the MRA.

3.2.2 You must send the MAH all AEs/PCs/SRSs that are raised during market research that relate to their medicinal products whether or not:

- they are serious or severe (and to what degree)
- you've established a causal relationship between them
- anyone else has already reported them to the MHRA
- the patient information leaflet or summary of product characteristics state that the AE is expected
- specific patient identifiers are present
- they relate to individual patients or to groups of patients

3.2.3 If you become aware of an SRS, you must forward it to the MAH, whether or not an AE or PC is associated with it.

If an SRS relates to a reported use of counterfeit or falsified medicines or tampering, you should consult with the MAH to make sure that these medicines are collected appropriately.

See Annex 1 for examples of AE, PC and SRS reporting scenarios.

3.2.4 It's important that you achieve highly accurate reporting, so collect as much information as possible about i) the market research participant reporting the AE/PC/SRS ii) the person that experienced it (if different) and iii) the AE, PC or SRS itself. Remember that you must comply with data protection legislation when doing so. See Annex 5 for information on this.

You must also ask whether the market research participant consents to the MAH contacting them for pharmacovigilance follow-up or use an alternative lawful basis for transferring the market research participant's personal data to the MAH.

Subject to data protection requirements, you must also keep a record of all AEs, PCs and SRSs that you send to the MAH and be able to produce this when required. You can use the reconciliation form template in Annex 4 to do this.

4 THE PROCESS

4.1 What must you report?

The information below that you must report to the MAH has no personal data associated with it, so there are no data protection issues. However, if a disease or condition is particularly rare then even very minimal information, when linked together, could be sufficient to identify someone. In this case (where information not normally considered to be identifiable personal data becomes personal data), you should make sure you're complying with data protection legislation.

4.1.1 Always forward at least the following (for an individual patient or a group of patients):

- The name of the medicinal product concerned
- A description of the AE/PC/SRS experienced

The MAH should make available to the MRA a list of relevant medicines for which it holds a marketing authorisation in the UK including the generic and brand name.

4.1.2 Try to collect and forward the following about the medicinal product and patient concerned:

- Dose
- Duration
- Indication of use
- Batch number
- Patient identifiers, specifically age/age group and gender

4.2 When do you need consent or an alternate lawful basis?

You can only send the following personal data to the MAH (under the Data Protection Act 2018) if the market research participant has given their consent or there is an alternate lawful basis in place. If you are depending on consent, consent must be secured before any data is transferred to the MAH; patients must give explicit consent as they are providing special category personal data (please see Annex 5 for the definition of "special category personal data).

- Full name (with title)
- Occupation
- Address
- Contact details

If the market research participant does not give consent, you cannot send this information to the MAH. The individual can still take part in the market research and you must report any AE/PC/SRS to the MAH as an anonymous report.

See Annex 6 for examples of wording you can use to obtain consent from different types of market research participants.

Remember that when you collect information about an AE/PC/SRS from a market research participant that relates to someone else's experience e.g. from a carer, you must report it to the MAH without the personal details of the individual who experienced it. (They have not consented to their details being used.)

4.3 How do you report?

Use an AE/PC/SRS reporting form to capture the information from market research participants straight after the interview. There is no need to interrupt interviews to complete these. If the research participant is

an HCP, they can complete the form themselves. Otherwise your agency fieldworker should complete the form and the research participant should sign it.

The MAH will give you the appropriate AE/PC/SRS reporting forms. See Annex 3 for a standard example.

Occasionally, and after consulting the MAH, you may be able to provide the AE/PC/SRS data in tables rather than on reporting forms, particularly if it is to be reviewed in aggregate or a large volume of AEs/PCs/SRSs is expected.

Market research agencies must keep a record of all AEs, PCs and SRSs sent to the marketing authorisation holder so that reconciliation can be performed as required. Reconciliation may be facilitated by use of a form such as that in Annex 4.

4.4 When must you report?

- Within one business day of the MRA or their subcontractor becoming aware of it

4.5 Are there any exceptions to the AE/PC/SRS reporting obligations?

The only exception is in:

- syndicated studies based on either primary or secondary market research – where data are collected independently of an individual company and are available for purchase by a number of pharmaceutical companies who haven't influenced the original design. Suppliers are not obligated to report AEs/PCs/SRSs; only the MAH is responsible for reporting to the regulatory body any AEs, PCs or SRSs associated with its products.

- longitudinal patient databases – anonymous patient level data extracted from the healthcare records of a sample of physicians and covering an extended period of time (normally a number of years).

  Companies access information in longitudinal patient databases for many reasons. These Guidance Notes only considers access to these databases for market research purposes.

  A MAH's access to a longitudinal patient database that may contain information qualifying as an AE/PC/SRS does not automatically mean they must buy the database or make them responsible for assessing the whole database in order to collect individual patient safety information.

  When the database is used by a MAH, data supplier, MRA, subcontractor or other analyst acting on behalf of the MAH, they do not need to report individual AEs/PCs/SRSs within the database[5].

[5] Guideline on Good Pharmacovigilance Practices (GVP) – Module VI – Collection, Management and Submission of Reports of Suspected Adverse Reactions to Medicinal Products (Rev 2) – EMA 873138/2011.

ANNEXES

ANNEX 1 REPORTING SCENARIOS FOR AEs and PCs

<table>
<tr><th></th><th>Situation</th><th>Collect?</th></tr>
<tr><td>1</td><td>During an interview, a market research participant taking Drug X for osteoarthritis in her knee indicates that she discontinued use of Drug X due to headaches.</td><td>Yes. The headaches are an AE.</td></tr>
<tr><td>2</td><td>A patient focus group is exploring which brand style concept to us for a diabetes portfolio. A patient in the focus group describes her experience of vomiting when taking Drug X. This stimulates discussion amongst the four other participants who each share different AEs experienced when taking Drug X.</td><td>Yes. Report each AE expressed by a patient.</td></tr>
<tr><td>3</td><td>Company X’s drug sales aids are being tested prior to roll out in a face-to-face interview. An HCP mentions that he has heard that patients can suffer from seizures and that this can be a problem.</td><td>No. The HCP has not indicated an AE for a particular patient or a group of patients.</td></tr>
<tr><td>4.</td><td>A survey is conducted to understand reasons behind prescribing habits in patients with asthma: “Please specify why you switched your last patient from Drug X to Drug Y.”

<table><tr><td>1</td><td>Lack of efficacy</td><td>3</td></tr><tr><td>2</td><td>Rash</td><td></td></tr><tr><td>3</td><td>Diarrhoea</td><td></td></tr><tr><td>4</td><td>Care giver preference</td><td></td></tr></table></td><td>Yes. Lack of drug effect can be an AE or a PC</td></tr>
<tr><td>5</td><td>Market research product consumer track question: “The X drug that I currently take does not work as well as it used to.” Market research participant indicates, “Strongly agree”.</td><td>Yes. Lack of drug effect can be an AE and a PC.</td></tr>
<tr><td>6</td><td>During a face to face interview, a market research participant states: “I’ve heard that Drug X can cause problems related to weight gain and high cholesterol levels and I’ve taken patients off of Drug X for this reason.”</td><td>No. This is anecdotal; the HCP does not indicate an AE for a particular patient or a group of patients.</td></tr>
<tr><td>7</td><td>In an online survey, an HCP market research participant states, “I switched from Drug A to Drug B because Drug B is a better product”.</td><td>No.</td></tr>
</table>

	Situation	Collect?
8	A patient focus group is discussing awareness of disease related symptoms. A market research participant indicates that, “fatigue is common in these types of patients”.	No. No drug is mentioned.
9	In response to the question, “In the last month, what percentage of your patients taking antidepressant X, have experienced headache?” an HCP states, “50%”.	Yes. HCP indicates an AE for a particular group of patients.
10	In a usage and awareness study, study participants are asked to indicate, for a series of attributes, how they would perceive a product in comparison to other products for the same indication. One of the attributes is, “this product causes nausea,” and on a five point scale ranging from, “much less than the other products shown, “to “much more than the other products shown.” The market research participant has ticked, “much more than the other products shown”.	No. Although the response infers that adverse event may occur with the product, this does not indicate an AE for a particular patient or group of patients.

ANNEX 2 EXAMPLE OF MARKET RESEARCH CONTRACT CLAUSE WORDING RELATING TO AE/PC/SRS REPORTING REQUIREMENTS.

Note: This example does not include any clauses related to Data Protection. You should ensure that your contract includes appropriate clauses relating to Data Protection legislation.

In this example Clause the following terms are used with the following definitions. You should expect such definitions to change in accordance with the terms used in your specific market research agreement.

Service Provider means the market research agency providing the market research services on behalf of the Client;

Client means that company that has commissioned the market research.

Adverse Event means 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 temporarily associated with the use of a medicinal product, whether or not considered related to the medicinal product.'

Product Complaint means any alleged failure of a product, including identity, durability, reliability, safety, efficacy or performance. It is specific to the product itself or its packaging, as opposed to its effect on the patient, including but not limited to:

- 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
- The identification of a potentially counterfeit medicine

Special Reporting Situation means any of the following situations:

- Exposure through a parent ie. drug exposure to a foetus in utero (whether the foetus is exposed because the mother took the product during pregnancy or transmission from semen following the father's exposure to the product)
- Use of a medicinal product during pregnancy or breastfeeding
- Reports of overdose, abuse, misuse
- Lack of therapeutic efficacy including suspected use of counterfeit/falsified medicines/tampering
- Medication errors (including dispensing errors, accidental exposure, maladministration etc.)
- Unapproved, or off-label use of a product ie. intentional medical use that doesn't comply with the authorised product information (including off-label use in children or the elderly)
- Withdrawal syndrome

A company may also indicate to the MRA that it considers the following to be an SRS and the MRA should make sure it understands exactly how the company defines this:

- Unexpected therapeutic benefit (the pre-existing condition improved)

Please also send the MAH any information received relating to these safety situations:

- Drug or drug-food interactions
- Suspected transmission of an infectious agent
- Occupational and environmental exposure (as a result of a professional or non-professional occupation)

Project means [**INSERT BRIEF PROJECT DESCRIPTION**]

Clause [*] – Adverse Event Reporting.

1. If during the course of planning, performing or reporting on the research, the Service Provider is informed of any Adverse Event, Product Complaint or Special Reporting Situation ("***Reportable Event***"), relating to any of the Client's products, the Service Provider should use the adverse event reporting form attached as Appendix [*] of this Agreement to report the same to the Client.

a. Completed adverse event reporting forms should be stored by the Service Provider for a period of [*] or such other period as may be agreed between the parties, taking into account the requirements of the Data Protection Act 2018 and any other applicable legislation.

b. At the lapse of the period referred to in Clause 1(a) above, the parties will agree the appropriate method of destruction and/or deletion of the adverse event reporting forms.

2. In forwarding to the Client information about Reportable Events, the Service Provider shall at all times take into account the requirements of the Data Protection Act 2018 and all other requirements set out in Clause [*] of this Agreement.

3. The Client shall determine whether the Reportable Event is required to be added to the Client's drug safety register.

4. The Service Provider shall provide a summary of all Reportable Events forwarded to the Client on a [**INSERT APPLICABLE INTERVAL**] basis.

5. The Service Provider will ensure that all of its employees, agents and representatives, including any sub-contractors, have undertaken pharmacovigilance training to a standard acceptable to the Client.

6. Notwithstanding the generality of Clause 5, the Service Provider shall provide up to date certificates of competency for all of its employees, agents and representatives, including any sub-contractors, working on the Project, in relation to pharmacovigilance reporting.

ANNEX 3 AE/PC/SRS REPORTING FORM TEMPLATE

Adverse Event / Product Complaint / Special Reporting Situation (AE/PC/SRS) Report - UK Market Research (HCPs or non-HCPs)

Please complete as many details as possible and **forward within one business day** to your pharmaceutical company contact **even if there is no identifiable patient**

Agency and Project Details

Market research agency and address:	Date aware of the AE/PC/SRS:
	Project title and / or Agency reference no:
Agency telephone no:	MAH reference number / Company project ID:
Agency email:	Respondent ID or AE/PC/SRS no:
Researcher's name:	Researcher's signature:

Drug and Event Details

Drug name(s):

Indication (condition for which the drug(s) prescribed: Unknown ☐	Adverse Event(s)/Product Complaint/Special Reporting Situation details*:
Dose: Unknown ☐	
Was the patient pregnant? Yes ☐ No ☐ Unknown ☐	Lot/Batch No.: Unknown ☐
Reported to the MHRA: Yes ☐ No ☐ Unknown ☐	Does the HCP/patient think the event might have been related to the drug? Yes ☐ No ☐ Unknown ☐

Patient Details

Age or year of birth:	Other:
Sex: Male ☐ Female ☐	

No. of patients: Individual patient ☐ Multiple patients ☐ State no. of patients if known:

(only tick 'multiple patients' if no individual identifying details are available; otherwise please complete separate forms

Respondent Details

I agree to my details being passed to the pharmaceutical company's safety team so that they may contact me to discuss this report further?

Yes ☐ Respondent signature:

No ☐

If respondent does not agree to their contact details being passed on, just complete the type of respondent

Name:	Doctor ☐
Address:	Nurse ☐
	Pharmacist ☐
Telephone no:	Patient ☐
	Carer ☐
Email address:	Other ☐ Please specify:

* e.g. other medicines taken by the patient, relevant medical history, event outcome, action taken with the medicine, was the patient hospitalised?

ANNEX 4 AE/PC/SRS REPORTING RECONCILIATION FORM

Reconciliation Form

Adverse Event / Product Complaint / Special Reporting Situation (AE/PC/SRS) Reports

Researchers should complete this form at the end of the market research project

Project Title & Reference:	
MAH Ref. No. / Company Project ID	
Agency / Company Name:	
Telephone No:	
Email Address:	
Researcher's Name:	
Researcher's Signature:	
Date:	

This is a summary of AE / PC / SRS reports submitted to the Company's Drug Safety Department.

Event No	Respondent ID	Product(s)	AE/PC/SRS Details
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
Total number of Adverse Events Reported:			

For any additional events please continue on an additional form - thank you.

ANNEX 5 KEY POINTS ON HANDLING PERSONAL DATA FOR AEs, PCs AND SRSs

You must always handle AEs, PCs and SRSs containing personal data in accordance with the applicable data protection laws.

This is not a guide to complying with that legislation. It is some general information to help you understand an MRA's obligations in handling personal data in AE/PC/SRS situations.

What is personal data?

This is defined as *'any information relating to an identified or identifiable living individual'.*[6]

What is a special category of personal data?

This is personal data that is particularly sensitive and therefore requires additional protection. The following are considered special categories of personal data under the General Data Protection Regulation:

- Racial or ethnic origin
- Religious or philosophical beliefs
- Trade union membership
- Genetic data
- Biometric data for the purpose of uniquely identifying a natural person
- Data concerning health
- Data concerning a person's sex life or sexual orientation

Data protection principles

The Data Protection Act 2018 sets out a number of principles that form the main responsibilities for organisations processing personal data. It states that personal data must be:

- processed lawfully, fairly and in a transparent manner in relation to individuals
- collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes. Further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall not be considered to be incompatible with the initial purposes
- adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed
- accurate and, where necessary, kept up to date. Every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay
- kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed. Personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes subject to implementation of the appropriate technical and organisational measures required by the GDPR in order to safeguard the rights and freedoms of individuals
- processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures

[6] Data Protection Act 2018, Section 3(2).

What are the lawful bases for data processing?

When a MRA becomes aware of an AE/PC/SRS, it is normally under a contractual obligation from the MAH to provide it with information about AEs/PCs/SRSs. In order for the MAH to follow up with the individual who reported or experienced the AE/PC/SRS, the information that the agency transfers to the MAH must include personal data.

The processing of personal data must be 'lawful'. There are six potential lawful bases for data processing[7]. Consent is the one most commonly used for the purposes of AE/PC/SRS reporting (although not the only one) if the report includes the transfer of personal data to the MAH. Consent means that the market research participant must have given consent to the transfer of their personal data to a MAH.

Other legal grounds that may be relied upon for processing personal data for drug safety reasons include:

- compliance with legal obligations eg. pharmacovigilance obligations (Article 6(1)(c));
- for reasons of public interest (Article 6(1)(e), (Article 9(2)(i));
- legitimate interests (Article 6(1)(f)) - although this basis cannot be used for the processing of special category data.

If processing a child's personal data there are specific provisions that must be taken into account, see Article 8 of the GDPR[8].

If the patient is deceased, data protection requirements do not apply[9].

What are the requirements for valid consent?

There are specific legal requirements for consent to be valid. Importantly, it must be separate from all other consents the market research participant has given relating to the market research. This consent must be verifiable so the MRA should keep a record of it. For further details of the what constitutes consent please see the BHBIA's 'GDPR Updates' on the 'Legal grounds for data processing' and 'Consent for market research' available on the BHBIA's website[10].

Under the Data Protection Act 2018, when relying on consent in order to process personal data, the organisation receiving and transferring it must be named when that personal data is obtained. Consent for processing personal data for AE/PC/SRS purposes may be obtained at the end of the interview as this is not essential to participation in the market research; it is a separate data processing operation.

Unnecessary duplicate copies of personal data collected for the AE/PC/SRS purposes should not be transferred or stored.

When processing personal data in market research, the following points are very important:

- Data protection impact assessment – as health-related information is a 'special category of information', MRAs should consider whether this is necessary
- Technical and organizational measures – when processing AEs/PCs/SRSs, the MRA and MAH should consider what is in place (proportionate to the sensitivity of the data and the risk of harm) to safeguard personal data. This includes both physical (eg. locked doors) and virtual (passwords and encryption security) as well as virus and perimeter protection (eg. firewalls). Use of a file transfer protocol site may be appropriate
- Effective data destruction policy – MRAs should not keep AE/PC/SRS reports containing personal data for longer than essential and should therefore have this policy in place. The contract with the MAH may also set out information management requirements, including secure deletion and other requirements set out in data protection legislation relating to an MRA's handling of personal data. These may take the form of a data processing agreement.

[7] General Data Protection Regulation; Regulation (EU) 2016/680, Article 6(1).
[8] General Data Protection Regulation; Regulation (EU) 2016/680, Article 8.
[9] General Data Protection Regulation; Regulation (EU) 2016/680, Recital 27.

- Detailed records – MRAs should also keep these on third party data processors that may collect AEs PCs and SRSs, consents secured, denied and withdrawn and any personal data processing carried out for the purpose of AE/PC/SRS reporting

Please note: Interpretation of GDPR and Data Protection Act 2018 requirements may change as regulators such as the Information Commissioner's Office provide further interpretation and guidance. Consequently these Guidelines may be subject to change.

[10] BHBIA GDPR Updates - Legal grounds for data processing, Consent for market research, www.bhbia.org.uk

ANNEX 6 EXAMPLE WORDING FOR USE IN MARKET RESEARCH INTERVIEWS IN RELATION TO AE/PC/SRS REPORTING.

The following gives you example wording to use with market research participants when:

- informing them that the MRA will give the MAH details of any AEs/PCs/SRSs
- asking if they are willing for the MRA to give their contact details to the MAH should an AE/PC/SRS come to light during the research

This wording is for information only and is neither mandatory nor constitutes legal or regulatory advice.

You should work with the MAH to agree:

- the appropriate privacy notice that the MRA should give market research participants
- when to give the privacy notice
- appropriate record keeping of the privacy notice given to them

6.1 Recruiting an HCP to participate in market research

PLEASE NOTE: This is not a fully formed consent agreement and you will need to add further specific detail eg. the name of the recipient company. For more information about consent agreements please see the BHBIA's GDPR Update on Consent for market research or section E4.2 of the BHBIA's Legal and Ethical Guidelines.

Example Wording

Interviewer says:

This research has been commissioned by a company that manufactures medicines. It is a legal requirement that the company keep records of any side effects or complaints that people may have about their medicines. We must assist the company in meeting its legal obligations.

Therefore, if, during the interview, you make any reference to a side effect or complaint about a medicine, we will let the company know about this even if it has already been reported by you directly to the company or the regulatory authorities. You can decide whether or not to give the company your name and contact details.

Please confirm the following statement:

"I agree that if I discuss any side effect or complaint about a medicine during the market research, this information will be passed to the company."

Next Steps

1. Interviewer should i) obtain confirmation from the HCP market research participant that they are happy to proceed on this basis and ii) keep a record of the confirmation.

2. If the HCP does not provide confirmation, they should not be recruited to participate in the market research. Interviewer should thank them and end the recruitment process.

3. If the HCP provides confirmation and raises an AE/PC/SRS during the interview, the MRA should seek confirmation from them that they can forward their contact details to the MAH. See Annex 6.3 for an example of the wording for this.

6.2 Before an HCP participates in market research

Use this after recruiting the HCP and before they participate in the market research.

PLEASE NOTE: This is not a fully formed consent agreement and you will need to add further specific detail eg. the name of the recipient company. For more information about consent agreements please see the BHBIA's GDPR Update on Consent for market research or section E4.2 of the BHBIA's Legal and Ethical Guidelines.

Example Wording

Interviewer says:

This research has been commissioned by a company that manufactures medicines. It is a legal requirement that the company keep records of any side effects or complaints that people may have about their medicines. We must assist the company in meeting its legal obligations.

Therefore, if, during the interview, you make any reference to a side effect or complaint about a medicine, we will let the company know about this even if it has already been reported by you directly to the company or the regulatory authorities. You can decide whether or not to give the company your name and contact details.

If you do provide your name and details with the AE, please rest assured everything else you say during the course of the survey will remain confidential.

Are you happy to proceed with the survey on this basis?

1. *Yes*
2. *No*

Next Steps

1. Interviewer should obtain confirmation (1. Yes) from the HCP market research participant that they are happy to proceed on this basis.

2. If the HCP does not provide confirmation, they cannot participate in the market research. Interviewer should thank them and end the participation.

3. If the HCP provides confirmation, the market researcher carrying out the interview should obtain a signed statement from them to that effect. Here is an example of the wording for this:

   DATE:

   NAME:

   STATEMENT: I understand that if I raise any AE/PC/SRS during the research interview, this information will be passed to the pharmaceutical company that commissioned the research. I confirm that this was explained to me before participating in this market research and that I was given the option not to take part in the research but that I decided to participate on this basis.

   SIGNATURE:

4. If the HCP provides confirmation and raises an AE/PC/SRS during the interview, the MRA should seek confirmation from the HCP that they can forward their contact details to the MAH. Please see Annex 6.3 for an example of the wording for this.

6.3 When an HCP raises an AE/PC/SRS during market research

Use this at the end of the market research interview and not during it.

PLEASE NOTE: This is not a fully formed consent agreement and you will need to add further specific detail eg. the name of the recipient company. For more information about consent agreements please see the BHBIA's GDPR Update on Consent for market research or section E4.2 of the BHBIA's Legal and Ethical Guidelines.

Example Wording

Interviewer says:

You previously confirmed that you agreed to information about AEs, PCs and SRSs that you may raise during participation in the market research, being provided to the company that has commissioned this research.

During this interview you described a situation that would be categorised as an AE, PC or SRS. I would therefore like to confirm to you that we will now pass this information to the company.

In order to further assist with medicines safety monitoring, [NAME OF COMPANY] may want to contact you directly to ask some follow-up questions. Please could you confirm that you consent to [NAME OF AGENCY] giving [NAME OF COMPANY] your contact details for any further follow-up.

Please confirm the following statement:

"I confirm that I consent to my name and contact details being passed to [NAME OF COMPANY] in the case that there is a need to follow up on the AE, PC or SRS raised during this interview."

Next Steps

1. If the HCP confirms their agreement, the interviewer should obtain a written record of this.

2. If the HCP confirms that contact details cannot be given to the MRA, the interviewer should say:

   Thank you. I confirm that I will not pass your contact details to the company.

6.4 Recruiting a patient/caregiver to participate in market research

PLEASE NOTE: This is not a fully formed consent agreement and you will need to add further specific detail eg. the name of the recipient company. For more information about consent agreements please see the BHBIA's GDPR Update on Consent for market research or section E4.2 of the BHBIA's Legal and Ethical Guidelines.

Example Wording

Interviewer says:

This research has been commissioned by a company that manufactures medicines. It is a legal requirement that the company keep records of any side effects or complaints that people may have about their medicines. We must assist the company in meeting its legal obligations.

Therefore, if, during the interview, you make any reference to a side effect or complaint about a medicine, we will let the company know about this even if it has already been reported by you directly to the company or the regulatory authorities. You can decide whether or not to give the company your name and contact details.

Please confirm:

"I agree that if I discuss any side effect or complaint about a medicine during the market research, this information will be passed to the company."

Next Steps

1. Interviewer should i) obtain confirmation from the market research participant that they are happy to proceed on this basis and ii) keep a record of the confirmation.

2. If the market research participant does not provide confirmation, they should not be recruited to participate in the market research. Interviewer should thank them and end the recruitment process.

3. If the market research participant provides confirmation and raises an AE/PC/SRS during the interview, the MRA should seek confirmation from them that they can forward their contact details to the MAH. See Annex 6.6 for an example of the wording for this.

6.5 Before a patient/caregiver participates in market research

Use this after recruiting the patient/caregiver and before they participate in the market research.

PLEASE NOTE: This is not a fully formed consent agreement and you will need to add further specific detail eg. the name of the recipient company. For more information about consent agreements please see the BHBIA's GDPR Update on Consent for market research or section E4.2 of the BHBIA's Legal and Ethical Guidelines.

Example Wording

Interviewer says:

As we previously discussed, it is a legal requirement that the company keep records of any side effects or complaints that people may have about their medicines. Please confirm that you agree that if you discuss any side effect or complaint about a medicine with us during the research, we will give this information to the company.

Next Steps

1. Interviewer should obtain confirmation from the market research participant that they are happy to proceed on this basis.

2. If the market research participant does not confirm, they cannot participate in the market research. Interviewer should thank them and end the participation.

3. If the patient/caregiver provides confirmation, the market researcher carrying out the interview should obtain a signed statement from them to that effect. Here is an example of the wording for this:

   DATE:

   NAME:

   STATEMENT: I understand that if I mention any side effect or complaint about a medicine, this information will be provided to the medicines manufacturer. I confirm that this was explained to me before participating in this market research and that I was given the option not to take part in the research but that I decided to participate on this basis.

   SIGNATURE:

4. If the patient/caregiver provides confirmation and raises an AE/PC/SRS during the interview, the MRA should seek confirmation from the patient/caregiver that they can forward their contact details to the MAH. Please see Annex 6.6 for an example of the wording for this.

6.6 When a patient/caregiver raises an AE/PC/SRS during market research

Use this at the end of the market research interview and not during it.

PLEASE NOTE: This is not a fully formed consent agreement and you will need to add further specific detail eg. the name of the recipient company. For more information about consent agreements please see the BHBIA's GDPR Update on Consent for market research or section E4.2 of the BHBIA's Legal and Ethical Guidelines.

Example Wording

Interviewer says:

We previously discussed the obligations that a medicines manufacturer has to keep records of any side effects or complaints that people may have about their medicines.

When you were answering the research questions, you mentioned that [INSERT BRIEF DESCRIPTION OF WHAT WAS SAID].

In order to find out more about the side effect or product complaint that you described, the medicines manufacturer might want to contact you directly to ask some follow-up questions.
Please could you confirm that you consent to us giving the medicines manufacturer, [INSERT MAH NAME], your contact details for any further follow-up. This is an information notice that gives you more information about how your contact details will be used.

Next Steps

1. If the patient/caregiver confirms their agreement, the interviewer should obtain a written record of this.

2. If the patient/caregiver confirms that contact details cannot be given to the MAH, the interviewer should say:

   Thank you. I confirm that I will not pass your contact details to the company.

6.7 The start of a market research internet study where HCP respondents can enter free text

Example Wording

PLEASE NOTE: This is not a fully formed consent agreement and you will need to add further specific detail eg. the name of the recipient company. For more information about consent agreements please see the BHBIA's GDPR Update on Consent for market research or section E4.2 of the BHBIA's Legal and Ethical Guidelines.

Interviewer says:

This study is sponsored by a pharmaceutical company and for this reason we are required to pass on any possible AEs, PCs and SRSs. The details of these will be reported anonymously unless you agree to disclose your personal details, only and exclusively for the purpose of follow-up by the client's drug safety team. Please select one of the options below:

- *I would like to proceed and agree to be contacted by the drug safety team for follow- up (PROCEED)*
- *I would like to proceed but do not wish to be contacted by the drug safety team for follow-up (PROCEED)*
- *I don't want to proceed and wish to end the interview here (THANK AND CLOSE)*