SCOPE Work Package 4
ADR Collection

Handling Telephone Calls from the Public

SCOPE

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Contents

Acknowledgments

Authors

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1. Introduction

1.1 Purpose of the document

As part of Work Package 4 (WP4), Review of Reporting Forms, a survey was circulated to all National Competent Authorities (NCAs) to collect information about telephone Adverse Drug Reaction (ADR) reporting processes. The results are summarised here in the survey results section of this document and in detail in 'Survey Report: Review of reporting forms'[1].

Many countries offer a telephone service for healthcare professionals and patients to call and report a suspected side effect; however, not all NCAs do. Potential issues that prevent NCAs from implementing a telephone service include worries over how to deal with difficult calls from members of the public, how best to capture all of the relevant information required for a high-quality ADR report and concerns around anticipated high volumes of calls that would need to be handled.

Following discussion of the survey results by WP4 members, a recommendation was made to design a telephone reporting toolkit. This toolkit was to include training for staff and recommendations on how to handle patient telephone reporting, along with practical advice about how to set up a telephone service and how to track the number and nature of the calls received. As such, this guidance is aimed at a range of NCA staff – from those that answer telephone calls, to their managers and the IT staff that can support this. It is recognised that much of the information provided through a telephone service will vary between NCAs, and so this guidance is intend.

1.2 Background

The Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action spanned over a three-year time period and was created to support operations of pharmacovigilance in Europe following the introduction of new requirements in 2012 European pharmacovigilance legislation. SCOPE gathered information and expertise on how regulators in Member States (MSs) run their national pharmacovigilance systems, in order to develop and deliver guidance, training, tools and templates to support best practice in pharmacovigilance. SCOPE aimed to support consistent approaches across the European Union (EU) network for all pharmacovigilance operations, which will benefit the safety monitoring of medicines and communications to safeguard public health.

SCOPE was divided into eight separate Work Packages (WPs), with five WPs focusing on pharmacovigilance topics to deliver specific and measureable objectives, ranging from improvements in ADR reporting to assessment of quality management systems.

[1] SCOPE, [Online] http://www.scopejointaction.eu/_assets/files/SCOPE-WP4-Topic-4-Survey-Report-v-0-7.pdf

WP4 specifically focused on national schemes for spontaneous reporting of ADRs and aimed to provide NCAs with a full understanding of best practice in systems for collecting ADRs. Information was gathered from European NCAs to understand their national pharmacovigilance Information Technology (IT) system capabilities, as well as implementation and development of patient reporting and electronic reporting, including those from clinical healthcare systems. This information was used to create a toolkit for MSs to raise awareness levels of ADR reporting systems, best practice guidelines, and performance indicators, which was supported through delivery of a training course for NCAs.

Within WP4, partners worked on five individual topics:

1. Audit of national reporting systems – lead: HALMED (Agency for Medicinal Products and Medical Devices of Croatia)
2. Patient reporting – lead: HALMED
3. Awareness levels – lead: MHRA (Medicines and Healthcare products Regulatory Agency)
4 Review of reporting forms – lead: MHRA
5. Review of IT systems and Special form of reports – lead: HALMED.

HALMED was the project lead on WP4 and was supported by the following active partners:

- AIFA (Italy)
- OGYÉI (Hungary)
- INFARMED (Portugal)
- MHRA (United Kingdom)
- NOMA (Norway)
- SMCA (Lithuania)
- SUKL (Czech Republic).

1.3 Regulatory requirements

Medicines regulatory authorities in the EU MSs adhere to legislation set by the European Parliament and the Council of the EU. As per Directive 2010/84/EU[2], NCAs have an obligation to improve ADR reporting in their region. Article 102 states that MSs shall:

a) *take all appropriate measures to encourage patients, doctors, pharmacists and other healthcare professionals (HCPs) to report suspected adverse reactions to the national competent authority; for these tasks, organisations representing consumers, patients and HCPs may be involved as appropriate*

b) *facilitate patient reporting through the provision of alternative reporting formats in addition to web-based formats*

c) *take all appropriate measures to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports*

d) *ensure that the public is given important information on pharmacovigilance concerns relating to the use of a medicinal product in a timely manner through publication on the web-portal and through other means of publicly available information as necessary*

e) *ensure, through the methods for collecting information and, where necessary, through the follow-up of suspected adverse reaction reports, that all appropriate measures are taken to identify clearly any biological medicinal product prescribed, dispensed, or sold in their territory which is the subject of a suspected adverse reaction report, with due regard to the name of the medicinal product, in accordance with Article 1(20), and the batch number.*

The Directive[3] directly addresses the expectations on each NCA to facilitate and improve reporting of ADRs. Without the collection of ADR reports with high-quality information, the ability to perform signal detection and thus protect public health is compromised.

Telephone reporting is a useful method for reporters to notify NCAs of ADRs, especially for people without access to computers or paper forms, for example elderly patients. Whilst newer, electronic methods and paper reporting are the most common mechanisms, telephone reporting is a valuable additional reporting tool that should offer reporters an easy way to provide detailed information. A dedicated telephone line also offers a way for NCAs to provide further information about their Agency and the work they do in monitoring the safety of medicines in their country.

[2] Official Journal of the European Union. [Online]. Available at: http://ec.europa.eu/health/files/eudralex/vol-1/dir_2010_84/dir_2010_84_en.pdf

[3] Official Journal of the European Union. [Online]. Available at: http://ec.europa.eu/health/files/eudralex/vol-1/dir_2010_84/dir_2010_84_en.pdf

1.4 Definitions and abbreviations

Terminology	Description
ADR	Adverse Drug Reaction
AIFA	Italian Medicines Agency
CHAFEA	Consumers, Health and Food Executive Agency
DKMA	Danish Health and Medicines Authority
EMA	European Medicines Agency
EU	European Union
FAQs	Frequently Asked Questions
HALMED	Agency for Medicinal Products and Medical Devices of Croatia
HCP	Healthcare Professional
INFARMED	National Authority of Medicines and Health Products
IT	Information Technology
LMP	Last Menstrual Period
MAH	Marketing Authorisation Holder
MHRA	Medicines and Healthcare products Regulatory Agency
MS	Member State(s)
NCA	National Competent Authority
NOMA	Norwegian Medicines Agency
OGYÉI	National Institute of Pharmacy and Nutrition
PIL	Product Information Leaflet
SCOPE	Strengthening Collaboration for Operating Pharmacovigilance in Europe
SMCA	State Medicines Control Agency
SOP	Standard Operating Procedure
SPC	Summary of Product Characteristics
SUKL	State Institute for Drug Control
WP	Work Package

2. Survey results

A web-based questionnaire was conducted to collect information on the availability of telephone reporting in each NCA. Responses showed that 19 out of 28 NCAs accept telephone reports and that 4 NCAs have a specifically tailored form for recording telephone reports. Less than 2% of NCA reports were received by telephone in 2013; however, the value of these services represents more than reporting alone. For further survey results and analysis, please see, Survey Report: Review of reporting forms[4].

[4] SCOPE, [Online] http://www.scopejointaction.eu/_assets/files/SCOPE-WP4-Topic-4-Survey-Report-v-0-7.pdf

3. Setting up a telephone messaging service

There are several considerations to be made when setting up a new reporting line or making improvements to a current system.

Firstly, consider how much staff resource you have available to deal with calls from members of the public. This can then help you decide if a telephone line is possible and, if it is, you can then determine what services you offer through your telephone line. For example, you may just want to accept reporting of ADRs or you may also respond to pharmacovigilance enquiries relating to ADR reports.

The Norwegian Medicines Agency (NOMA) accepts calls from members of the public; however, the NOMA telephone service is not intended for consumers to report suspected ADRs. Instead, if a consumer calls to submit a report, then they are directed to the online reporting form. If a consumer does not have access to the online form, they are asked to enlist the help of their next of kin or alternatively a physician or pharmacist to report on their behalf. When patient reporting was introduced in Norway in 2010, NOMA encouraged pharmacists to help consumers to report with the added bonus that more information is fed back to HCPs compared to patients.

If you do accept reports over the telephone, you may wish to only have the line operational for specific times during the day. For example, the UK Medicines and Healthcare products Regulatory Authority (MHRA) telephone service is only available 10am – 2pm.

Once the remit of the telephone line has been decided, then it will be important to ensure the naming of the telephone line in any promotional material reflects the purpose of the system, e.g. by calling it a 'reporting line'. It is important to decide if and how the telephone reporting option will be advertised (e.g. only on the NCA website or on guidance documents etc.), as the level of promotion of the service will impact the volume of calls received.

Next, the service needs to be developed. Start by having a dedicated phone number, ideally one that is free for members of the public to call and that can be accessed by all staff that will be monitoring the calls. It is then helpful to develop an automated telephone service to set expectations and to provide the caller with some basic information, prior to speaking with a member of staff. This may need to be developed with local NCA IT support.

A successful telephone messaging service should consider including the following:

- An initial welcome message, which can provide basic details of the service and set enquirers expectations, including what can't be provided, e.g. medical advice.
- Routing options – such as options to direct callers to the right place in case they do not wish to report an ADR, e.g. 'Press 1 to speak to an operator to report an ADR or find out more about the work we do', 'Press 2 to be directed to central enquiry point', etc.
- Next, depending on the enquirer's choice, they will be connected to an operator.

- Finally, consider having the ability to take answer phone messages – if the call is not answered, then an answer phone message can be triggered to explain to the enquirer what details to leave on the message and any actions to expect, e.g. whether the NCA staff will call them back. This is useful for when calls are missed or if the telephone lines are not monitored all the time, but again this will need to be considered in the context of available resource. It can be helpful to have 'out of hours' or public holiday answer messages, so the caller is routed immediately to leave a message without the need to let the phone ring out.

4. Training your staff

The qualifications of staff that answer calls will vary with each NCA, however, as no medical advice is provided, it is acceptable to train non-medics in answering these calls.

It can be quite daunting for new staff when they begin taking calls from members of the public. Putting a training programme in place can help to make sure that staff feel prepared and confident in their role, as well as enabling them to offer a valuable service. Provision of this SCOPE document, or a locally tailored version, can go a long way to training them, but it may also be worth providing face-to-face training, either from experienced staff or from external trainers. As part of WP4, an e-learning module with guidance on handling different types of calls is available on the SCOPE website.

5. Types of telephone calls that may be received

The main purpose of a reporting line is to accept ADR reports, however, people often also request information about the NCA and pharmacovigilance. This provides an opportunity to offer members of the public an insight into the work that is done to monitor the safety of medicines in their country and to promote spontaneous reporting schemes as part of this. Most calls will be from patients and HCPs and it will be important to adapt your tone and responses depending on the caller and the questions asked.

All calls should be received with an introductory sentence, 'Hello. You have reached the [NCA] reporting line, my name is [staff name]. How can I help you/would you like to submit a report of a suspected side effect?' The different types of calls can be considered as falling broadly into seven categories. Depending on the response of the caller the following general suggestions can be used:

Category 1: Reporting an ADR

If an enquirer calls to report a suspected ADR, then follow the guidance for handling these calls which is provided in Section 8: How to take down the details of an ADR report.

Category 2: Requesting information about the work of the NCA

If a caller requests further information about the work of the NCA, then follow the guidance provided in Section 11: Frequently Asked Questions.

Category 3: Requests for data

If a caller is requesting information regarding ADR data that can be provided, e.g. the number of reports received for a drug, then note down the request, including contact details, and tell them when a response should be received or direct them to where this is publicly available, if applicable. Guidance for handling these requests will be specific to each NCA based on what data can be provided and how these are handled.

Category 4: Requests from the media

Refer to local NCA Standard Operating Procedures (SOPs) for the policy for handling the media. Typically, it would be useful to take the details of their request down and advise when they should receive a response. This will enable the request to be documented for audit purposes and give an opportunity for the response to be approved by senior management, as necessary.

Category 5: Requests from members of the legal profession

Refer to local NCA SOPs for the policy for handling legal matters. Typically, it would be useful to take the details of their request down and advise when they should receive a response. This will enable the request to be documented for audit purposes and give an opportunity for the response to be approved by senior management, as necessary.

Category 6: Difficulties with online reporting (where online reporting is available)

This will vary according to local online reporting systems. If the caller has been having problems reporting online, take their details and let the caller know that the problem will be looked into by the technical team, if it can't be resolved over the telephone. You can offer to take down details of their report or ask them to try again at a later stage or via another reporting mechanism. If possible, then ask questions that might help the issues to be investigated. For example:

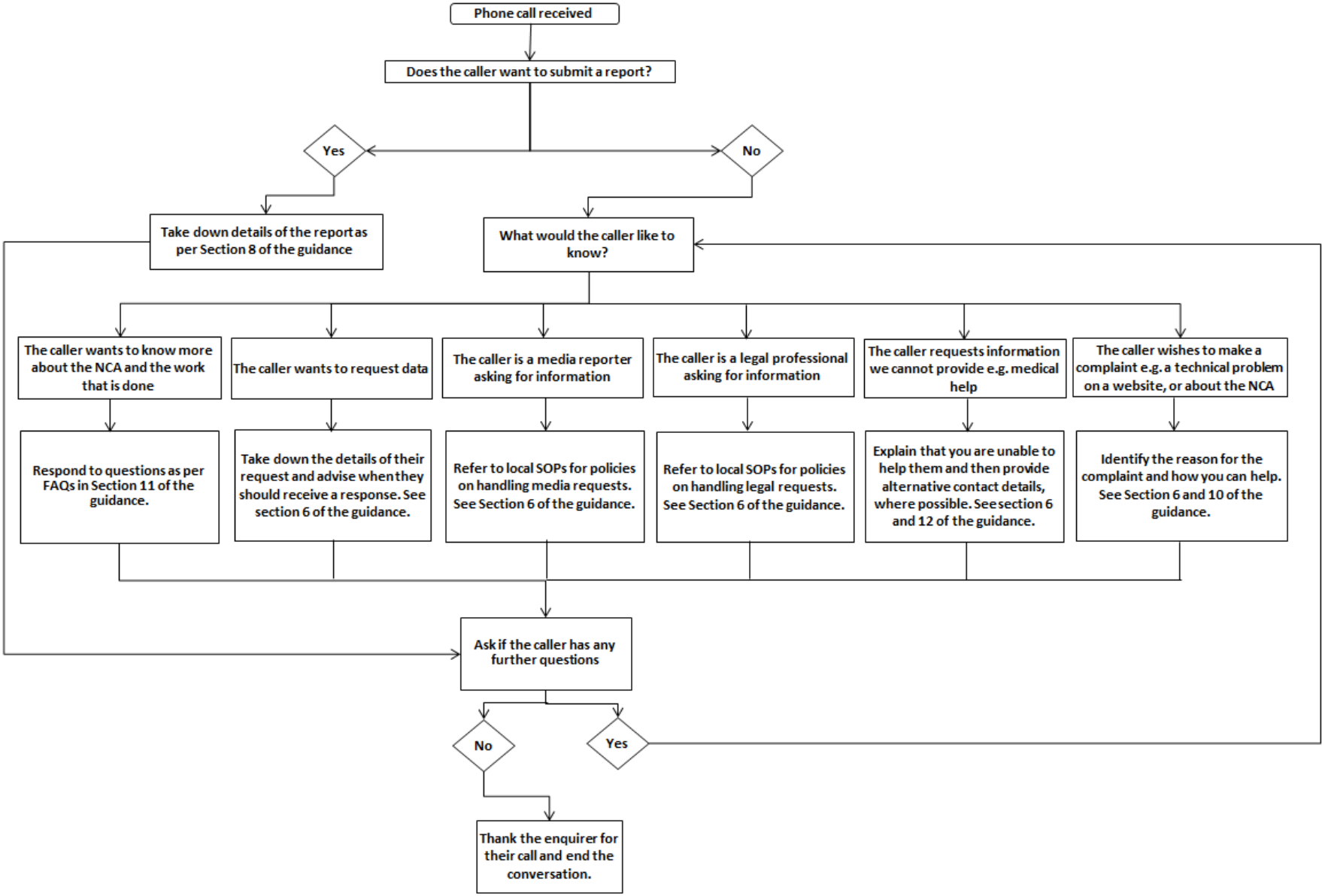
- Internet browser type and version (e.g. Internet Explorer, version 9)
- Date/time when the issue occurred
- Login information (email address only, no passwords should be taken) – to ensure the user's account is configured correctly
- Steps to reproduce error – exactly what the user did in order to arrive at the error
- Description of how the page looks on the latest step (sending a screenshot would be most helpful)
- Description of any error messages that were produced.

Category 7: Requests we are unable to help with

The purpose of telephone reporting is to accept ADR reports and to provide information about the NCA and pharmacovigilance; however, there will be times when someone asks for information you cannot provide. If it is not possible to help an enquirer, then make this clear in the conversation and direct them to an appropriate alternative contact, where possible. If a request for medical advice is made, then ask them to contact their doctor, pharmacist or medical helplines (see Section 11: Useful contacts to refer enquirers to).

Do not suggest that you can look into their questions further if you know that this is not part of your NCA's remit, as this wastes time and raises the enquirer's expectations.

6. Flow chart for responding to callers



The flowchart can used as a guide to refer to each of the sections.

Figure 1. Flowchart for responding to callers

7. How to take down the details of an ADR report

If the enquirer would like to provide details of a suspected ADR, it is important to note down as much information as possible during the telephone call to limit the need to follow up and enable high-quality signal detection to be carried out.

To avoid missing key details, it is helpful to ask questions in a logical and thorough manner. Explain to the caller that you will be going through a series of questions and advise roughly how long this will take. Taking down comprehensive details can be achieved by following a template, such as your NCA's paper or online form, making sure as a minimum that the mandatory information is provided. Asking questions using the NCA form will mean that questions are not missed and also the questions will follow a logical order rather than jumping between sections, which could confuse the caller and risk missing information. Whether you record the ADR details directly on to a paper form or type it in to a computer, this can form the source data, which should be recorded according to local SOPs.

Take care to record the reporter's own words in full, i.e. do not paraphrase, change the wording or miss out pieces of information, as this can distort or lose the meaning of the information. If questions have been asked, but the reporter cannot answer them, it is useful to record these as 'not applicable' or 'not known' to avoid unproductive follow-up. Sometimes, reports will relate to distressing symptoms or sensitive information, such as the passing of a loved one, and so it is important that you remain sensitive and professional at all times.

For some types of report it is vital to request specific information. This can be relevant for reports such as additional monitoring products, biologicals and vaccines, elderly or pregnant patients, as well as for reports of medication errors. It will be helpful for you to familiarise yourself with the key information needed in each scenario; suggestions are provided in **Table 1** below.

Table 1. Important information to receive for ADR reports

Type of ADR report	Important information to receive
Additional monitoring	Variable depending on medicine-specific risks
Biologicals	Brand name and batch number
Vaccines	Brand name and batch number
Pregnant mothers	Last menstrual period (LMP), due date, previous pregnancies, dates of ultrasound scans and any findings, other medications taken during pregnancy
Paediatric patients	Specific age in days, weeks or months
Medication errors	Reason for the medication error

At the end of the call it is useful to recap the details provided to make sure the reporter is happy with the account of their ADR. Thank them for contacting you and explain any next steps, such as if an acknowledgement will be sent, or let them know that follow-up may be requested at a later date.

Some NCAs seek to obtain medical confirmation from a HCP for all patient reports. In these cases it will be important to request the HCP contact details whilst on the phone, including an explanation of why this is helpful.

8. Monitoring calls

It can be helpful for staff to keep a log of calls by noting down information in a spreadsheet, including the types of calls, the durations and the outcomes. There are a number of benefits to recording this:

- It allows for analysis of the types of calls received in order to understand how your service is being used
- Common calls can be identified quickly, for example, if lots of calls request medical advice it might be worth making it clearer on forms and in communications that such advice cannot be provided
- Resource can be monitored easily, as the time taken to handle the call can be recorded, allowing you to manage resource effectively
- It can allow repeat callers to be identified quickly, as staff can review the logs whilst taking calls, which will be helpful, so they are aware of previous actions that have been taken.

If a log sheet is created then this should be updated by staff soon after the call is taken and ideally saved to a central point that is accessible to all staff that handle phone calls. An example of a log sheet is provided below.

Date	Time	Duration	Successful report submitted?	Name of caller	Suspected medicine	Patient or Healthcare professional	Details of the call	Member of staff who took the call
01/03/2016	10:00	15 minutes	No	Mrs Fiorelli	Ramipril	Patient	Wanted expert medical advice so I explained we aren't able to offer advice and suggested she speak to a doctor	Mr Fernandez
02/03/2016	13:45	10 minutes	Yes	Dr Novak	Simvastatin	Healthcare professional	Report submitted	Mr Fernandez

Figure 2. Example log for phone calls received by an NCA

9. Handling difficult callers

Some enquirers may be challenging and it is important to be prepared to handle this if the situation arises to avoid frustrating the caller and to protect yourself from difficult situations. Below are some tips on how best to handle specific types of callers.

Angry callers

- Allow callers to calm down and tell you what their concerns are. Ensure that you listen carefully and try not to interrupt, as this may antagonise them.
- Be patient and, once the caller has calmed down, ensure that you understand why they are angry and try to empathise with their concerns.
- Ask the enquirer what they expect from the call. It will then be easier to address the issues and explain what we can and can't help them with.
- Depending on the situation, you could consider asking the enquirer to call back when they have had a chance to calm down.
- Keep your voice calm, slow and low – do not raise your voice.

Abusive callers (different to angry callers as this relates to when a caller is being offensive, such as swearing)

- Do not let the caller continue to be verbally abusive towards you, but do not argue/be abusive back/hang up on them without warning.
- Explain to them that their behaviour is unacceptable; you may need to speak over them and say 'if you continue to use abusive language, I'm afraid I will have to finish this call'. If they continue, let them know you are ending the call before you hang up.
- Speak to a manager, so that they are aware of the issue and can provide support, if necessary.

Caller complaining about the service

- Allow the caller to calm down, if necessary, and listen to their complaint without interruption.
- Acknowledge what they have said – paraphrasing to show you have understood what they said.
- Make it clear you are listening to their concerns through repeating back and saying 'Yes' or 'I understand'.
- Ask open questions about their original expectations and what went wrong.

- Ask closed questions to check facts and times.
- Suggest options to take their complaint forwards – for example, it may be enough to provide a sincere apology or it might require pointing them in the direction of a formal complaints procedure.
- You can question the validity of their complaint – i.e. if they are complaining they were not given medical advice then politely explain that you can't provide this.
- Remember to thank them for their call and explain that the feedback they have provided is welcomed as this assists the continuing development of systems and processes.

Circular callers (callers who go over the same ground repeatedly)

- As early as possible, point out that it seems there is a lot to go through in detail and explain that the helpline is only able to spend a certain amount of time on this call – i.e. further information can be provided by post or email.
- Interrupt to acknowledge when information has already been mentioned in order to steer the conversation to the next subject or to close the call.
- Use 'us' and 'we' language, i.e. 'if we can move on to …'

Distressed callers

- Allow the caller to talk and give them time to calm down.
- Make it clear you are listening to their concerns through repeating back and saying 'Yes' or 'I understand'. Empathise with their problems.
- Try to steer the conversation to the caller to identify how you can help and to encourage them to provide details for an ADR report.
- Have to hand additional sources of reference for the caller to offer professional support.
- Use language such as 'us' or 'we'.

It can be hard on the member of staff handling difficult calls, so if you are upset by any conversations you have had then please discuss this with your manager or a colleague, so that support can be provided.

10. Frequently Asked Questions (FAQs)

It is important to be consistent when answering frequently asked questions (FAQs) and staff will benefit from having a resource document to refer to in order to achieve this. This can include typical phrasing for answering FAQs or alternative contacts and information sources to direct the caller to. Most of the details will be specific to each NCA, so it would be worth producing local FAQs. Sometimes, over the phone, you might want to summarise the answers and then point them in the direction of more comprehensive information or offer to post/email additional information to them.

Who monitors the safety of medicines?

Explain that your NCA is responsible for monitoring the safety of medicines. Depending on the enquirer, it may be useful to describe the pharmacovigilance process from receiving reports and entering them into a database or spreadsheet, through to signal detection and the range of outcomes possible.

Why might a medicine become available before all of its side effects have been identified?

Explain that before a medicine is licensed, it will be tested in clinical trials. Clinical trials will identify the more common and predictable side effects of medicines, whereas rarer side effects may only be seen once the medicine is used in a far larger and more diverse number of patients, under the conditions of everyday use. In addition, some side effects may only appear after prolonged use. This is why it is important to monitor medicines even after they have been licensed for use and update product information and guidance, as necessary.

If all medicines have side effects, surely this means no medicine is safe – why should I take any medicine?

Depending on the tone of the reporter, carefully explain that, yes, all medicines can have side effects. But, it is important to then explain the value of medicines. Firstly, the majority of people will not experience side effects and those that do tend to experience more common, mild reactions, which they will recover from.

Let the reporter know that the decision to take a medicine should be done with consideration of the benefits and risks of the medicine and that they should be making the decision along with advice from their doctor. Explain that medicines will help to treat or relieve symptoms, which can be worth the risk of ADRs. Often side effects will be more acceptable when treating more severe indications, and vice versa with milder indications.

Explain that when the NCA are considering whether a medicine should be granted a licence for use, the potential benefits of a medicine are looked at together with the potential risks, including the risk to the patient if the condition is not treated. The medicine will only be given a licence if the benefits of treatment are shown to outweigh the risks.

How are medicines monitored in order to ensure that previously unknown side effects are detected?

Tell the reporter that the collection of spontaneous suspected ADRs from HCPs, patients and pharmaceutical companies is an important way that we monitor medicines.

Explain that these suspected ADRs are then entered onto a specialised database or spreadsheet that allows us to process and analyse the reports rapidly. We evaluate the reports, along with other sources of information, such as studies, in order to identify previously unidentified potential ADRs and new information on recognised side effects. You might want to explain the local process for signal detection, e.g. how often reports are assessed and how decisions are made. Explain that the risks and benefits of the medicine are considered and, if necessary, action can be taken to ensure that the medicine is used in a way that minimises risks and maximises benefits to the patient.

Why do medicines have side effects/why have I experienced a side effect?

Start by explaining that all effective medicines have side effects, sometimes due to the way the medicine is intended to work, e.g. beta-blockers effectively reduce blood pressure, but in doing so can slow down the heartbeat too much.

Other potential side effects however can be unpredictable and, as patients are all individual and can respond in slightly different ways to the same medicine, it is often difficult to predict how effective a medicine will be in treating a patient's medical condition, and whether the patient will have any side effects.

Does submitting a report really does make a difference?

Clearly explain that yes, it does make a difference, and that it is a vital component in our ability to protect public health.

We need the reports to identify previously unrecognised side effects and ways in which the risks of recognised side effects can be minimised. Every report we receive contains useful information – without the reports, we simply would not be able to continue this important work.

It would be helpful to emphasise that a single report can make a difference. If you have some good examples of signals raised from a small number of reports, then this will help to add impact and persuade a person to submit a report.

What will happen to the report if I submit?

The pharmacovigilance process will vary with each NCA, but this is a good opportunity to engage the reporter. It is important to try to gauge the level of detail the caller is asking for, so start by explaining that their report will be entered into a database/spreadsheet by the team and that their report will be reviewed as part of a process known as 'signal detection', which is the identification of drug safety issues.

If they would like more detail on the pharmacovigilance process then you can explain that, when we identify a new possible side effect or learn more about a recognised one, we carefully consider this in the context of the overall side effect profile for the medicine. We also consider this in comparison with the side effects of other medicines that can be used to treat the same condition, and compare the risks with the benefits of the medicine as described above. If necessary, we may take action to ensure that the medicine is used in a way that minimises the risks and maximises the benefits to the patient. We might include details of a new side effect in the product information, reduce the dose to be used, or give out warnings about groups of patients who should not be given the medicine. In rare circumstances, we may need to withdraw a medicine from the market, when we believe that the risks of a medicine are greater than its potential benefits.

Since starting my medicine, I have noticed a number of new symptoms that I think may be due to the medicine. What do I do?

Advise them to contact their doctor, pharmacist or medical helplines (see Section 12: Useful contacts to refer enquirers to) to seek advice or treatment and offer to take down a report.

I think the symptoms I have experienced are reactions to my medicine, but my doctor doesn't agree. The symptoms came on after I started taking the medicine, so surely they must be side effects?

Start by acknowledging that if they are worried about their symptoms then they should seek medical help. Then explain that it can be difficult to determine if a medicine has caused a reaction, as symptoms can be related to other medical conditions, or may simply be coincidental, and normally it is not possible to confirm the causes of symptoms. If you have easy access, you could let them know whether the symptoms they have described are known side effects in the product information.

Finally, suggest to them that you can take down their details to submit a report for them.

My daughter was vaccinated last week and now she isn't herself, I don't know what to do

Start by finding out about the vaccine and the suspected ADRs the girl has experienced, taking down the report details as necessary, including brand name and batch numbers. If they are worried, or if the reaction is serious, then let them know that they should seek medical help.

Make it clear that your NCA takes the safety of vaccines seriously and continuously monitors their safety, as with all medicines. Explain that all vaccines are extensively tested for quality, safety and immunogenicity and/or efficacy before being licensed and used routinely.

Vaccines protect against a variety of serious diseases, which used to be much more common before vaccines were used. As most vaccines are administered to very large numbers of people every year, some recipients will experience illness following vaccination and underlying or concurrent illnesses may also be responsible.

The benefits of vaccines outweigh the risks and side effects tend to be mild, transient and common for most types of vaccine – for example sore arms, redness and swelling at the site of the injection, headaches and tiredness.

How do I get information on the known side effects of medicines?

Refer the caller to the Product Information Leaflet (PIL), which should be given with most medicines, and advise that this provides instructions on how the medicine should be used, and information on its possible side effects. State that they can also talk to a doctor, pharmacist or nurse, who should be able to tell them about the side effects of the named medicine.

You may want to direct them to an online source of PILs or Summary of Product Characteristics (SPCs), where available. Alternatively, you could suggest that the company who make the medicine can provide the product information on request; the company should be named in the PIL, but if possible you can search for contact details to provide to the caller whilst on the telephone.

Has anyone else reported a similar side effect with this medicine?

Refer the patient to publicly available data or take down the details of their request, so that this can be looked into and responded to in writing. This will be specific to each NCA depending on the data held and local data provision policies.

The MHRA have an Interactive Drug Analysis Profile – www.mhra.gov.uk/yellowcard – which lists the reactions for each spontaneous report associated with a particular drug. Guidelines are also provided to enquirers to ensure correct interpretation of the data, specifically that neither incidence nor causality can be concluded from the reports.

If I submit a report, will my doctor get a copy?

The process for informing HCPs about a patient report will vary with each NCA, but if this is an option then explain to the patient that, with their permission, a copy of the report will be sent to an HCP if they provide contact details.

It is important that you let the caller know that details of any report submitted will not be passed on without their agreement.

Does the report contain personal details about me?

The level of patient information retained will vary with each NCA. Explain the details that will be stored by your NCA and explain why certain information can be important to include. For example, contact details allow you to contact them if further information is required and patient characteristics are important to record for assessment of the case, as well as to allow HCPs that we have contacted (with the patient's permissions) to identify them. Additionally, age and sex is helpful when investigating the factors that may make certain patients more likely to experience a particular side effect. Patient and reporter confidentiality is a key feature of spontaneous reporting schemes and therefore it will be important to emphasise to the caller the importance of this and how an NCA adheres to data privacy laws in your country and the steps taken to ensure confidentiality is upheld at all times.

Can you tell me if my doctor has submitted a report about me?

The ability to identify patients will vary with each NCA. It will be important to explain the data privacy laws applicable to your NCA and reassure how confidentiality is upheld for all reports received. If applicable, tell them that, due to confidentiality, you are unable to confirm whether you have received a report about them, and that, if they want to know whether their doctor, pharmacist or nurse has submitted a report, they will have to speak to them directly.

This principle also applies for HCPs requesting information on their patients over the telephone. If they are not the reporter, or cannot provide sufficient information to identify them as such, then explain that you cannot give these details.

I am unhappy with the treatment from my doctor, what actions will you as the NCA take?

Explain that the NCA does not have a role in regulating clinical practice or investigating allegations of medical malpractice. If the caller has concerns or wants to register a complaint about an individual doctor, they can contact their clinical practice regulator.

It is important to combine this with an explanation of our actual role, which is that we are responsible for ensuring that medicines are acceptably safe and that, whilst we provide information for the safe use of medicines to HCPs, prescribing and clinical care is the responsibility of the HCP. The HCP is in the best position to decide on the appropriate treatment for the individual given their clinical expertise and knowledge of the patient.

Be careful not to antagonise the patient; if they are closed to explanations of why the doctor may have prescribed them a drug and why we cannot advise them, then try a more empathetic approach. You might want to suggest that they seek advice from a different HCP.

Can I request more paper reporting forms?

Guidance will be local to each NCA, however it should be easy for callers to request this. Take down their address and advise when they should receive these. It is also important to thank them for their support so they feel valued and happy to request forms in the future.

How do I know that you work for the best interests of the patient and aren't just doing what the Marketing Authorisation Holder (MAH) asks you to do?

Explain that the role of the NCA is to safeguard public health and that monetary or political factors are not a factor for consideration in the decision-making process. Provide reassurances by describing what local processes are in place to prevent conflicts of interest, for example NCA policies and how these are upheld.

An example response for the MHRA might be:

> *'The MHRA recognises the potential for conflicts of interests and as a result has a strict code of practice in place, which is outlined on our website. All staff members have to comply with the policy, which restricts them from having interests in pharmaceutical and medical technology industries.*
>
> *This policy also extends to chair people and members of committees, who must declare any conflicts of interests and in turn be excluded from relevant discussions. We also encourage patient representatives to attend and contribute to committees to aid the decision-making process.'*

If your NCA has a policy for handling conflicts of interest that is publicly available, then point the enquirer to where they can access this.

My dog has swallowed my heart medication, will he be OK? What should I do?

Human medicines are not intended for animals and they should be stored safely to prevent accidental consumption. Recommend that they contact their veterinarian for further advice. If they want to report an ADR for their pet then provide them with contact details for the veterinary medicines regulatory agency in your country.

My medicine hasn't worked, so I want to claim money back

NCAs do not have responsibility for the cost of medicines and cannot provide refunds, so make this very clear from the outset and explain what the NCA remit is. Take down the details of their report, making sure to ask for the brand and batch number, and consider coding the case as a report of lack of efficacy. You can direct them to contact the MAH of the product, although be clear that the MAH may not refund them the price of the medicine.

11. Useful contacts to refer enquirers to

Sometimes enquirers will ask questions that are not appropriate to the reporting line and it is helpful to have a list of local telephone, online or postal contacts to refer the enquirer to. It is helpful to draft local guidance on contacts for staff to refer to, and the lists below give some suggestions of what to include.

- Medical advice
  - Emergency Services
  - Non-emergency phone advice from trained medical staff
  - Health professionals, such as pharmacists – where to seek this help locally, e.g. a pharmacy
- Other NCA departments
  - Central Enquiry Point – to direct them elsewhere within the NCA
  - Other NCA divisions, e.g. devices, licensing
  - Complaints
- Patient support lines, disease charities
- Other government departments, e.g. food products, cosmetics, veterinary medicines regulators
- Responsible authorities for regulating clinical practice
  - Government authority for regulating clinical malpractice
  - Website to identify local hospital or practice contact details for making complaints.

12. Conclusions

SCOPE WP4 has identified, through surveys, that most countries accept telephone reporting and that, although it makes up a small proportion of all ADR reports, it is still an important method for receiving information and engaging with reporters. Telephone reports contribute to our ability to perform signal detection and identify safety issues and, thus, protect public health. This guidance document aims to help NCAs improve their telephone reporting mechanisms through provision of a toolkit, including training for staff and recommendations on how to handle patient telephone reporting.

The guidance provided here will enable NCAs to develop local guidance and set up a telephone system that provides a valuable telephone service.