

# **SCOPE Work Package 4**

## **ADR Collection**

**Raising and Measuring  
Awareness Levels for  
ADR Reporting Systems  
through Campaigns  
and Regional  
Monitoring Centres**



**SCOPE**

# SCOPE Work Package 4

## ADR Collection



## Raising and Measuring Awareness Levels for ADR Reporting Systems through Campaigns and Regional Monitoring Centres

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## Acknowledgments

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## 1. Introduction

### 1.1 Purpose of the document

This document provides an overview of campaigns run by National Competent Authorities (NCAs) to raise awareness of their national ADR reporting systems and how their effects on awareness are measured. Example case studies were identified from the information supplied by NCAs in response to the SCOPE survey on awareness levels. These examples are provided in a separate document for ease of referral. Together these documents aims to complement existing practice, provide some inspiration on approaches to consider, and to encourage NCAs to consider such campaign activities, including initiatives from regional monitoring centres. The guidance also aims to showcase approaches and tools to consider when measuring the success of an ADR campaign.

### 1.2 Definitions and abbreviations

Terminology	Description
ADR(s)	Adverse Drug Reaction(s)
EC	European Commission
CPD	Continuous Professional Development
DHPC	Direct Healthcare Professionals Communications
EMA	European Medicines Agency
GP(s)	General Practitioner(s)
HCP(s)	Healthcare professional(s)
KPI	Key Performance Indicator
MHRA	Medicines and Healthcare products Regulatory Agency (UK)
MAH	Marketing Authorisation Holder
MedDRA	Medical Dictionary for Regulatory Activities
Patient	Members of the Public – includes patients, parents and carers
MS(s)	Member State(s)
NCA(s)	National Competent Authority(s)
NHS	National Health Service (or Systems)
PAR	Public Assessment Report
PIL	Patient Information Leaflet
PV	Pharmacovigilance

Terminology	Description
RSS	Really Simple Syndication / Rich Site Summary
SCOPE	Strengthening Collaboration for Operating Pharmacovigilance in Europe
SmPC or SPC	Summary of Product Characteristics
WP	Work Package

### 1.3 List of attachments

Ref No	Document name	Author(s)
Annex 1	Raising Awareness of National ADR Reporting Systems: Survey Report	Mitul Jadeja, Paul Barrow
Annex 2	Good practice point to consider when developing an effective communications campaign	Mitul Jadeja, Paul Inglefield
Annex 3	MHRA's Yellow Card Strategy	Mitul Jadeja
Annex 4	Yellow Card campaign phase 1 Master Content Final	Mitul Jadeja
Annex 5	An example template for MSs to consider using when planning communications messages with stakeholders	Mitul Jadeja, Paul Inglefield
Annex 6	Know your medicines – example methodology from Medicines Authority (Malta)	Malta
Annex 7	Direct translation of GØR MEDICIN MERE SIKKER, AFRAPPORTERING (Make medicines safer reporting campaign) document into English using Google translate	Danish Medicines Agency. Translated using Google Translate into a document by Mitul Jadeja
Annex 8	Yellow Card Phase I evaluation report – GPs, community pharmacy and patients	MHRA Mitul Jadeja, Paul Barrow, Rheannon Pinder
Annex 9	Yellow Card Phase II evaluation report – paediatrics	MHRA Mitul Jadeja, Paul Barrow, Milony Shah
Annex 10	Raising Awareness of National ADR Reporting Systems: Case Studies by Country	Mitul Jadeja with input from NCAs

## 1.4 Disclaimers

Some screenshots are of 'literal' translations of the original material generated by Google Translate. However, one but should be able to infer the message intended for the reader. It is recommended that a web browser be used, when accessing the URLs, that can automatically translate other languages into the default language of the reader. Screenshots within this document have been taken using Google Chrome Version 49.0.2623.110 m.

All URLs contained within this document were live when accessed on 10/11 June 2016.

Information used within this guidance is based upon analysis of the responses from Member States to the SCOPE survey. It also includes information gathered from further follow-up requested by the WP4.3 author. Follow-up was conducted to gain further insight, documentation and information about responses. If no information was provided at the time of the survey responses or upon subsequent follow-up requests it will not be reflected within the WP4.3 content. As a result case studies vary in the level of detail.

## 2. Snapshot of survey results

NCAAs were asked a series of questions relating to their campaign work, including the duration, messages, activities, partners and channels used to increase awareness levels. Below is a summary of the findings.

### 2.1 Types of campaigns

- Sixty-two campaigns were organised by 10 NCAAs
- One NCA accounted for 41 campaigns – many were small scale projects and initiatives, such as holding a local workshop run by a regional centre
- Nine NCAAs organised 21 campaigns of which 17 (81%) were run at a national level
- Many examples were given on the implementation of additional monitoring, and the rest were reporter-specific, e.g. pharmacists or patients.
- 61% of NCAAs (17) indicated they haven't run a patient campaign. Shared examples within this document may stimulate such campaign work.

### 2.2 Duration

- Campaigns lasted for an average of 8.9 months.
- Some ranged from a few weeks to 24 months.
- Many were approximately three months long.

### 2.3 Collaborations, messages and tactics

- Thirteen NCAAs (62%) collaborate with healthcare professional (HCP) organisations for campaign work
- All campaigns included the importance of ADR reporting as a message
- The most common forms of tools used in campaigns were online websites and printed communication
- Social media and e-learning were not used as often to raise awareness. Social media is a potential tool that NCAAs may wish to consider using to reach wider audiences to raise awareness levels.

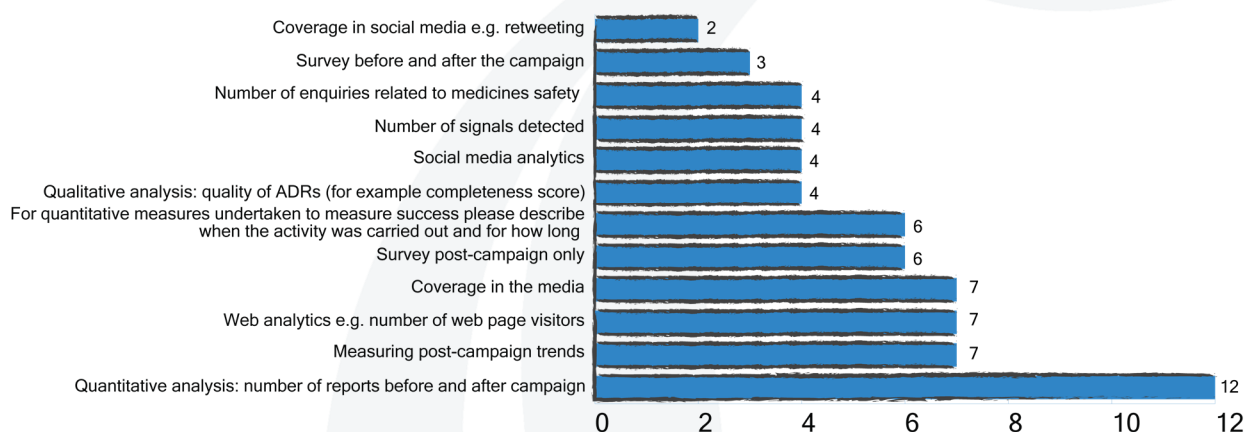
## 2.4 Measuring success

Within the SCOPE WP4.3 survey (Q20-Q23 and Q43-Q47), NCAs were asked a series of questions relating to:

- How campaign success was measured
- How the campaign was rated according to the objectives
- Which activities were the most successful
- Which activities were the least successful
- If the effectiveness of any awareness activities was measured
- Describe how effectiveness was measured

This information was analysed and the results can be found within the SCOPE WP4.3 survey report under the section measuring success ([Annex 1](#)).

Of 21 campaigns, 13 (62%) included measures of success. A further 4 campaigns were ongoing (19%) and 4 were not measured (19%). After follow up, a total of 7 NCAs indicated and described how the success of their campaign activities were measured. The mean success rate of the campaigns indicated by 9 NCAs was 6.7 out of 10.



**Figure 1.** The ways in which NCAs indicate they measure ADR campaign success

*Respondents included: CZ, DK, FR, GR, HR, IS, LV, NL and UK.*

The majority of methods used to measure success focused on the output of communications campaign activities. This can be a good indicator of immediate feedback on success. However, it is suggested as good practice to measure outcomes, though these may be more challenging to measure. For example, measuring the changes in behaviours and attitudes of reporters for those targeted by the campaign. Such measurement may not be always infer direct results attributable to the campaign. However it can be used to assess the reach of messages and their quality. This information can be used to further tailor and improve both the messages and approaches for future activity.

## 3. Running an ADR Communications Campaign

### 3.1 Campaign definition

Within the SCOPE Work Package 4.3 survey, a 'campaign' was defined as a:

*'Planned or coordinated series of actions (to increase awareness levels and reporting) within a defined period of time.'*

### 3.2 Good practice points

As a result of information provided by NCAs, a 'Good practice points to consider when developing an effective ADR communications campaign' was developed. This can be found in [Annex 2](#).

NCAs may wish to consider the various areas outlined within the points to consider guide when planning their own communications campaign to increase the number of suspected ADR reports and increase awareness levels of their respective national reporting systems.

#### 3.2.1 High level topics

High level topics within the: 'Good practice points to consider guide for developing an effective communications campaign' are:

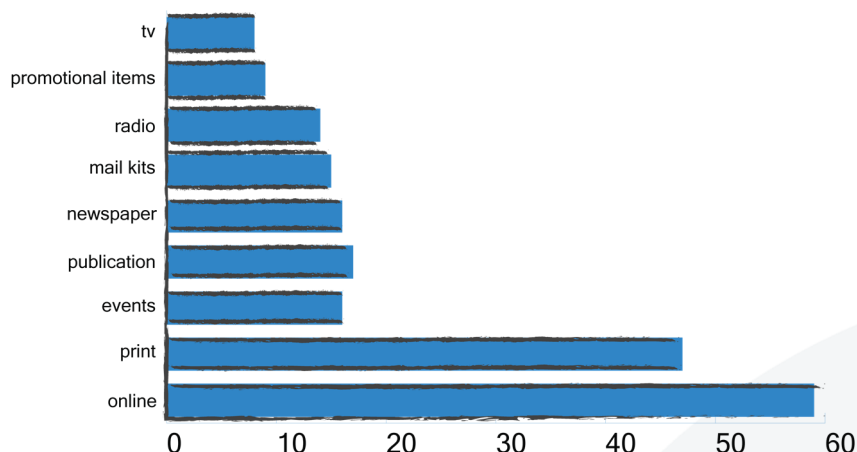
- The Strategy
- Situation analysis
- Aims and objectives
- Target audiences
- High level key messages
- Channels - overview
- Budget
- Challenges, risks and mitigation
- Evaluation
- The Action Plan
- Detailed key messages
- Channel selection
- Establishing roles and responsibilities

NCAs may also wish to consider a simple template when communicating with stakeholders to plan individual messages. An example is in [Annex 5](#).



### 3.3 Channels overview and tactics

NCAAs use a variety of communication channels when running an ADR campaign. A high-level graph shows the grouped channels NCAAs indicated they have used.



**Figure 2. Grouped communication channels used during campaigns by NCAAs**

A more detailed analysis of how NCAAs indicate they promote ADR reporting can be found within the SCOPE WP4.3 survey report ([Annex 1](#)). For example, the promotional items used in campaigns were pens (many NCAAs), mouse pads (Greece), badges and notepads (Denmark).

A variety of channels and tactics used by NCAAs to encourage suspected ADR reporting.

- Bulgaria – a poster presentation and dispelling ADR reporting myths
- Croatia – radio
- Croatia – theatre production – a focus on paediatrics
- Czech Republic – videos, postcards and posters
- Denmark – learning website with videos
- Hungary – interactive presentation
- Ireland – congress and a special award
- Latvia – a book on PV
- United Kingdom – use of online forum for doctors
- United Kingdom – use of social media examples and digital banners

Further information and case studies on each of these can be found in [Annex 10 Raising Awareness of National ADR Reporting Systems: Case Studies by Country](#).

### 3.4 Additional monitoring to raise awareness

Many campaign examples provided by NCAs within the SCOPE 4.3 survey were around the implementation and announcement of additional monitoring. Examples were provided by Hungary, Latvia, Norway, the Czech Republic and the UK. Often materials were coupled with a very simple message, such as that ADRs to additionally monitored products should be reported, or how to report ADRs.

Channels for such messages were added into NCAs' websites, news items and safety newsletters, EMA videos and leaflets, FAQs, and lectures to HCPs explaining the importance of additional monitoring and encouraging them to report. The UK used Twitter to disseminate key messages around additional monitoring and to provide a link to their reporting system.

### 3.5 Patient-related campaigns

Patients have a significant potential to add value to PV as a major reporting group.

The following NCAs indicated running patient-related campaigns to raise awareness of their national ADR reporting systems:

- Croatia
- France
- Ireland
- Netherlands
- United Kingdom

To encourage NCAs to consider running their own campaigns, specific case studies on these campaigns can be found in [Annex 10 Raising Awareness of National ADR Reporting Systems: Case Studies by Country](#).

### 3.6 Targeted campaigns

Targeted campaigns, mainly aimed at healthcare professionals, were run by the following NCAs:

- Czech Republic – Physicians and their bodies
- Denmark
  - Doctors in general practice and medical students
  - Psychiatrists, psychiatric patients and their relatives
  - Nurses and carers
- France – Paediatric medication errors campaign
- Latvia – Physicians, pharmacists and other healthcare professionals
- United Kingdom
  - Phase 1 – Public awareness campaign, focusing on pharmacies and GP surgeries
  - Phase 2 – Public, GPs and pharmacists follow-up
  - Phase 3 – Targeting other groups – paediatrics

Each of these case studies can be found in [Annex 10](#).

## 4. Regional Monitoring Centres raising awareness

Seven NCAs indicated that Regional Monitoring Centres (RMCs) operate in their respective countries. These NCAs are (in alphabetical order): Norway, France, Italy, Portugal, Slovenia, Spain and the United Kingdom.

All NCAs indicated that their RMCs raise awareness levels of their ADR reporting systems, be it local or national, depending on the set up. All RMCs collect suspected ADR reports with the exception of the UK who have centralised this into the core PV functions of the MHRA.

NCAs were also asked to describe the contribution of raising awareness activities by RMCs. In addition to this, NCAs were asked how respective efforts are coordinated, about budgets, and whether their effectiveness is measured. Table 1 summarises this information.

Most regional centres focus almost all activity on healthcare professionals (HCPs). Norway, France and the UK indicated that its regional centres interact with patient stakeholders to raise awareness levels.

Table 1. High-level overview of the contribution from RMCs within the seven NCAs

	France	Norway	Italy	Portugal	Slovenia	Spain	United Kingdom
Number of centres	31	5	16	4	2 (1 on vaccines only)	17	5
Process suspected ADR reports	Y	Y	Y	Y	Y	Y	N
Conduct education or training			Y	Y	Y		Y
Promotion of reporting	Y	Y	Y			Y	Y
Funding		funded by State	funded by AIFA	funded by Infarmed	funded by government		funded by MHRA
HCPs stakeholders	Y	Y	Y	Y	Y (doctors)		Y
Patients stakeholders	Y	Y					Y
Other comments (e.g. how they are managed or extra information)	managed by regional Health Agencies	ADR trends used to monitor; conduct CPD activities for HCPs	monitoring program ongoing which is in a pilot phase	biannual reports on activity indicators	focus on awareness and vaccines; One RMC focuses only on vaccines	indicators agreed by working group, annual reports produced	objectives agreed annually; contracts in place; annual reports, quarterly telephone calls

*Blank cells indicate no information was provided on this activity. Extra information from follow-up has been added to this table as appropriate.*

[Annex 10 Raising Awareness of National ADR Reporting Systems: Case Studies by Country](#) also looks at each of the seven NCAs in turn in alphabetical order. It describes example practice, case studies and initiatives of RMCs to raise local awareness of suspected ADR reporting.

## 5. Measuring the success of ADR campaigns

### 5.1 Why measure success?

It is important when evaluating the success of an ADR campaign to refer back to the initial strategy goal(s). The aim of the strategy is to increase reporting and the quality of suspected ADR reports through raising awareness levels. The purpose of an ADR communications campaign is to change individual behaviours and attitudes, to educate patients and HCPs about the national reporting scheme and the NCA, in order to increase reporting. Where relevant, the communications campaign may help to support a sustainable change in policy through partnerships or influencing. For example, through interacting with professional bodies one can help support the addition of, or strengthening of their formal guidance for HCPs on the reporting of suspected ADRs. The ultimate impact of any activities and messages should be so that reporters move towards a better patient safety culture where reporting is not an afterthought but as second nature; part of normal practice and policy.

Evaluation of any communications campaign is an area that poses spontaneous suspected ADR campaigns a major challenge for NCAs. Assessing the impact and value of campaign efforts helps one to know how to work better, gain organisational support, evaluate costs and resources, realistically examine any lessons learnt to work out what works well and what didn't work as well as envisaged in the planning stages. Such analysis can enable future planning for strategy and communications plans to be more efficient, effective and adaptable and better tailored to the audience receiving the messages.

### 5.2 What can be measured?

Measuring an increase in reports simply involves monitoring and measuring the change over time (before and after the campaign) in the number of direct spontaneous suspected reports received by the national ADR reporting system. However, often an increase in the numbers of suspected ADR reports is not seen immediately.

It is suggested as good practice that measuring success is built into the initial planning stages rather than only being considered towards the end of a campaign. By setting a target to aim for as part of a strategic objective, it is also good practice to indicate what will be measured for an activity and how it will be measured, including the use of any tools and resources that might be needed.

Benchmarking may be a useful way to measure activity or perceptions before and after completing an activity. Measurement using the same approach in both instances can enable similar comparisons to be made to identify any changes. If no changes are present, the approach or messages might need to be tweaked.

It is also good practice to build into the planning stages exercises to engage with the intended audiences and their representatives, in order to test messages. This can help to ensure any messages that are received by the audience are relevant, meaningful and have a greater chance of changing behaviour in order to increase reporting. User testing in this way might also reveal other methods to measure success. NCAs may also wish to consider this as a way to further influence, collaborate and partner with stakeholders to promote suspected ADR reporting for the campaign.

It is good practice to review and incorporate main communications into a Quality Management System approach. This can help reduce time spent planning for the future campaigns. It also helps refine messages so they are more efficient and effective. It can also aid better interaction and engagement with audiences to facilitate a better uptake of messages.

NCAs may wish to consider measuring the following in relation to communications activities to promote suspected ADR reporting:

- **Outputs** – e.g. numbers of posters, books, leaflets, partnerships, distribution figures, collaborations, etc.
- **Key messages and out-takes** – e.g. where to report, understanding of the concept of reporting, understanding the value of reporting, the effect of reporting. Out-takes focus on who was reached comparing what was produced. For example, what's the circulation is on an article? How many people viewed an activity? Who downloaded a video? What the attendance was at an event?
- **Outcomes** – changes in suspected ADR reporting numbers; changes in behaviours, attitudes and opinions that can be measured.

As a rule of thumb, try to measure as much as possible with the resources available. Although measurement of outputs and out-takes are improving, reaching audiences is rarely the end goal and so it is good to also focus on measuring outcomes and ultimately changes in behaviour.

There are many guides and models available online for measuring general communication campaigns, which NCAs may also wish to consider<sup>1</sup>. Campaigns and strategic work may also effect other parts of the NCA which can also be considered to include in evaluating success.

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<sup>1</sup> Evaluating Your Communication Tools What Works, What Doesn't? The Westminster Model:  
[http://www3.westminster.gov.uk/Newdocstores/publications\\_store/communications/evaluating\\_your\\_comms\\_aw\\_lr-1319206316.pdf](http://www3.westminster.gov.uk/Newdocstores/publications_store/communications/evaluating_your_comms_aw_lr-1319206316.pdf) accessed 18 April 2016.

### 5.3 NCA examples and evidence of good practice

Many NCAs monitor the numbers of suspected ADR reports received when measuring their campaigns. Those NCAs that described how effectiveness was measured for their awareness raising activities are described in [Annex 10](#). These include:

- Croatia
- Denmark the campaign evaluation of ‘make medicines safer – report side effects’ can be found in [Annex 7](#)
- Estonia
- France
- Greece
- Iceland
- Malta an example of the methodology and use of polls, interviews, surveys and results are shown in [Annex 6](#)
- Netherlands
- Sweden
- United Kingdom

Two examples of post-campaign evaluation reports are provided in [Annex 8](#): Yellow Card Phase I evaluation report, and [Annex 9](#): Phase II evaluation report.



## 5.4 Checklist to measure campaign success

It is suggested that NCAs consider a post-campaign evaluation report outlining success, measures and lessons learnt to shape future campaign and strategy objectives. NCAs may also wish to hold frequent meetings to manage the direction of the campaign and to achieve its goals.

Table 2. Key areas, corresponding measures and tools for measuring the success of a campaign, identified from SCOPE WP4.3

Key Areas	Measures	How
<b>Suspected ADR reports</b>	Monitoring the number of reports before and after, or over time	Dashboards, management reports, numbers over time
<b>Signals</b>	Monitoring the number of signals before and after	Dashboards, periodic signals review, PRAC signals, regulatory action, changes to SPCs, addition to PSURS, RMPs
<b>Attitudes and behaviour</b>	It is important to do this before and after any campaign. Changes in behaviour and views	Benchmarking through, surveys, polls, interviews, workshops, focus groups, logging feedback through action plans, CAPAs, yes or no surveys, quantitative scaled questionnaires, heuristic tests
<b>Enquiries</b>	Monitoring the number of enquiries before and after	Dashboards and management reports, customer service surveys, logging feedback, using 'contact us' form on website
<b>Quality analysis of ADRs</b>	Develop a score for monitoring effectiveness of message (e.g. a message to reporters about including the batch number), compare before and after for completeness of fields.	WHO vigiGrade completeness score, WEB-RADR Clinidoc scoring, quality audit results
<b>Website evaluation</b>	Web analytics to monitor trends over time, site search terms, downloads, views, etc.	Using analytical software such as Google analytics, Webtrends
<b>Press/Media</b>	Efficacy of campaign, scoring of press/news items, number of published articles or blogs including their reach and statistics	Management reports, record keeping, press monitoring, Barcelona declaration principles (AMEC)
<b>Newsletters</b>	Number of people distributed to, views, opens, reads, clickable links	Use distribution lists, web trend software, use a mailing list tool

Key Areas	Measures	How
<b>Partnerships &amp; collaborations</b>	Numbers of partnerships made, number of meetings, outputs of collaboration, outcomes, projects and campaigns. Connecting with partners to retweet a coordinated social media developed message	Management reports, exploring attitudes and behaviours from feedback and with members of organisations, through meetings, surveys, conferences, campaigns
<b>Feedback</b>	From workshops, organisations, bodies, consultative input, congresses	Reports, enquiries, qualitative analysis, discussion forums, polls, surveys
<b>Social media</b>	monitoring over time the number of views, retweets, likes, submissions or shares, polls, follows, followers, opportunity to see figures, numbers of blogs, RSS subscribers, Facebook fans, number of comments, other online mentions	Management reports, dashboards, simple counts and software tools, tweets over time
<b>Distribution</b>	Queries and number of reports received back, analysis of reports received from geographical locations	Dashboards, monitoring and trend statistics, feedback, heat maps
<b>Congresses / lectures</b>	Numbers of people spoken to, numbers signed up to newsletters, numbers influenced, partnerships and introductions made, logging feedback	Monitor ADR reports, dashboards, management reports, feedback

## Annexes

### **Annex 1. Raising Awareness of Adverse Drug Reaction Reporting Systems: Survey Report**



WP4-3 Survey  
Report layout draft

### **Annex 2. Good practice points to consider when developing an effective communications campaign**



Annex 2 Good  
practice points to cc

### **Annex 3. Yellow Card Strategy 2011**



Yellow Card  
Strategy 2011.pdf

### **Annex 4 Yellow Card Strategy Update 2013 and a paediatrics communications strategy**



Yellow Card  
Strategy 2013 updat

### **Annex 5. An example template for MSs to consider using when planning communications messages with stakeholders.**

Below is an example used by the MHRA. In this instance, the stakeholder is the ABPI. MHRA needed ADR reporting guidelines to be changed in response to additional monitoring.

Who	Why	Their needs	What action we want them to take
ABPI	ABPI code of practice refers to adverse event reporting mechanisms and needs amending	<ul style="list-style-type: none"> <li>To know what the changes are</li> <li>To know when they will be taking place</li> <li>Guidance for handling inquiries from their members</li> </ul>	<ul style="list-style-type: none"> <li>Update Code of Practice</li> <li>Highlight changes to members</li> <li>Support members to meet the requirements</li> </ul>

#### **Annex 6. Know your medicines – example methodology from Medicines Authority (Malta)**



Annex 6 Know Your  
Medicines - Malta.pdf

#### **Annex 7. Direct translation of GØR MEDICIN MERE SIKKER, AFRAPPORTERING (Make medicines safer reporting campaign) document into English using Google translate**



Annex 7 DKMA  
Campaign evaluation

#### **Annex 8. Yellow Card Communications campaign Phase I evaluation report – GPs, community pharmacy and patients**



Annex 8 – Yellow  
Card communication

#### **Annex 9. Yellow Card communications campaign Phase II evaluation report – paediatrics**



Annex 9 - Yellow  
Card communication

#### **Annex 10. Raising Awareness of National ADR Reporting Systems: Case Studies by Country**



Raising Awareness  
of National ADR Rep