

# **SCOPE Work Package 4 ADR Collection**

## **Paper ADR Reporting Forms**



**SCOPE**

# SCOPE Work Package 4

## ADR Collection:

### Paper ADR Reporting Forms



## Contents

Acknowledgments	3
1. Introduction	4
1.1 Purpose of the document	4
1.2 Background	4
1.3 Regulatory requirements	6
1.4 Definitions and abbreviations	7
2. Survey results	9
3. Points to consider when designing a form	11
3.1 Prototype development	11
3.2 User testing	12
3.3 Content of the form	17
3.4 Layout and design	19
3.5 Language used	20
3.6 Types of form	20
4. Guidance, background and supplementary information	29
4.1 Introduction on why to report suspected ADRs	29
4.2 What to report	30
4.3 How reports are used	30
4.4 Who to report to	30
4.5 Methods of reporting	30
4.6 How to complete a form	30
4.7 Medical advice	31
4.8 Links to further information	31
5. Availability	33
6. Feedback	34
7. Conclusions	35
Annex 1. Fields to include on a paper form	36

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### Authors

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## 1. Introduction

### 1.1 Purpose of the document

As part of Work Package 4, 'Review of Reporting Forms', a survey was circulated to all National Competent Authorities (NCAs) to collect information about paper Adverse Drug Reaction (ADR) reporting forms currently in use by NCAs. The results are summarised here in the survey results and in detail in 'Survey Report: Review of reporting forms'.<sup>1</sup>

Most European countries offer a paper reporting form for patients and healthcare professionals (HCPs) to inform their NCA of a suspected side effect. In 2012, the European Medicines Agency (EMA) pharmacovigilance legislation was updated and, along with it, a number of requirements upon NCAs were revised and added. Some of the changes, for example expanding the ADR definition to include medication errors, meant that many reporting forms needed updating.

As NCAs may update their paper forms in response to legislation changes, stakeholder feedback and changes in local NCA processes, as well as the potential to introduce new targeted forms, a recommendation was made to provide guidance on producing paper reporting forms.

This guidance discusses points to consider when designing a new or updated form and provides examples of good practice from the European Union (EU) NCAs, which can be used as a point of reference for NCAs when tailoring a form for their own requirements.

This guidance complements the 'The form of the form'<sup>2</sup>, delivered by the Uppsala Monitoring Centre (UMC).

### 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 requirements introduced by 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 EU network for all pharmacovigilance operations, to benefit the safety monitoring of medicines and communications to safeguard public health.

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

<sup>2</sup> <http://www.who-umc.org/graphics/28521.pdf>

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

WP4 specifically focused on national schemes for spontaneous reporting of ADRs and aimed to provide National Competent Authorities (NCAs) with a full understanding of best practice with regard to 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 reporting through 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 the delivery of a training course for NCAs.

Within WP4, there were five individual topics which partners worked on:

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 MSs adhere to legislation set by the European Parliament and the Council of the European Union. As per Directive 2010/84/EU<sup>3</sup>, 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<sup>4</sup> directly addresses the expectations of each NCA to facilitate and improve reporting of ADRs. Without collection of ADR reports with high-quality information, the ability to perform signal detection, and thus protect public health, is compromised.

Paper reporting forms were the original method for reporters to notify NCAs of ADRs. Although newer, electronic methods are now popular in many countries, paper forms continue to be an essential reporting mechanism that should offer reporters an easy way to provide detailed information and NCAs should factor this in to their pharmacovigilance activities.

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<sup>3</sup> 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](http://ec.europa.eu/health/files/eudralex/vol-1/dir_2010_84/dir_2010_84_en.pdf)

<sup>4</sup> 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](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
BCG	Bacillus Calmette–Guérin
BNF	British National Formulary
CHAFAEA	Consumers, Health and Food Executive Agency
CIOMS	Council for International Organizations of Medical Sciences
DKMA	Danish Health and Medicines Authority
EMA	European Medicines Agency
EU	European Union
EV	EudraVigilance
GP	General Practice
GVP	Guideline on good pharmacovigilance practices
HALMED	Agency for Medicinal Products and Medical Devices of Croatia
HCP	Healthcare Professional
HPRA	Health Products Regulatory Authority
INFARMED	National Authority of Medicines and Health Products
IT	Information Technology
MA	Medicines Authority
MHRA	Medicines and Healthcare products Regulatory Agency
MS	Member State(s)
NCA	National Competent Authority
NOMA	Norwegian Medicines Agency
OGYÉI	Hungarian National Institute of Pharmacy and Nutrition
SCOPE	Strengthening Collaboration for Operating Pharmacovigilance in Europe
SMCA	State Medicines Control Agency

Terminology	Description
SPCs	Summary of Product Characteristics
SUKL	State Institute for Drug Control
UK	United Kingdom
UMC	Uppsala Monitoring Centre
URPL	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
WP	Work Package



## 2. Survey results

At the start of the SCOPE Joint Action, a web-based questionnaire was conducted to collect information on the paper forms currently used by each NCA. Responses from 26 NCAs with paper forms found many similarities, however there are differences in the layout and content of each form. The results of the survey are briefly summarised here; for in-depth results and analysis, please see ‘Survey Report: Review of reporting forms’<sup>5</sup>.

Twenty-six NCAs have paper forms; just one NCA does not having this reporting option available. There was variation in the number of forms used by each NCA. 16 NCAs have a generalised form for all reporters, 7 have one specific to HCPs and 6 have a form specific to patients. However, there are also examples of additional forms; for example, the most frequent additional form was for vaccines (11 NCAs), followed by medication errors (5 NCAs) and biologicals (1 NCA).

When developing paper forms, 11 NCAs carried out studies for HCP forms and 9 for patient forms. NCAs also benefitted from referring to other NCA forms as a guide, running pilots with user groups and consulting with pharmacovigilance committees and regional centres.

The layout and formatting styles vary; however all NCAs use a form that is A4 or A5 and between one and two pages long. In five NCAs these forms are produced in multiple languages. Typically, the forms clearly show the NCA logo, branding and address, in addition to the information requested.

All paper forms include fields that make up the minimum criteria required by the Guideline on good pharmacovigilance practices (GVP) Module VI<sup>6</sup> for a valid report; at least one identifiable reporter, one single identifiable patient, at least one suspect adverse reaction and at least one suspect medicinal product. The patients permission is sought to inform their doctor and to allow follow-up with the patients’ doctor on some NCA paper forms, although this is in the minority (7 NCAs).

Guidance on completing the form, either by short explanatory texts on the form itself or on separate forms, is provided by 21 NCAs, and 15 also include background and supplementary information.

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<sup>5</sup> SCOPE, [Online] <http://www.scopejointaction.eu/assets/files/SCOPE-WP4-Topic-4-Survey-Report-v-0-7.pdf>

<sup>6</sup> EMA, [Online] Available at: [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2014/09/WC500172402.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2014/09/WC500172402.pdf)

Methods to distribute paper forms included making them available at regional centres, pharmacies, hospitals, and General Practice (GP) surgeries. 8 NCAs include their paper forms in specialist publications and a handful of NCAs stated that reporters can access the forms from other agencies (4 NCAs), by downloading them from their website (2 NCAs), attaching the form when sending responses or acknowledgments (2 NCAs) and within bulletins (1 NCA). The forms are mainly posted, including free postage in 11 NCAs; however, 6 NCAs also have fax and email options.

Several NCAs have made changes to their forms in the last five years and these updates have been made when necessary owing to changes in legislation, stakeholder feedback and changes in local NCA processes.

As a result of this survey, we have identified examples of paper forms from NCAs, many of which have been used to demonstrate good practice and are provided later in this guidance document.

## 3. Points to consider when designing a form

Designing or updating a paper form can seem like an easy task; however, there are a number of ways to achieve a successful form and the finished product will vary depending on the target audience and the aims of the form.

There are a number of reasons why you may want to design a new or updated paper form. Firstly, a new form may be required if you decide to focus on a different requirement, such as having a dedicated vaccine form. Secondly, due to changes in legislation, such as the inclusion of medication error questions. Finally, you may wish to change it based on feedback from users and staff to improve the form.

In the simplest of terms, a paper form needs to facilitate collection of information regarding a suspected ADR from a reporter to an NCA. To achieve this, a form must allow a reporter to enter the information he or she feels is important, including the information needed by the NCA to perform signal detection. One of the biggest barriers to reporting is the time taken to fill in a form, and so this needs to be addressed by ensuring the form is clearly designed, written in plain language and quick and simple to use. Points to consider are discussed below.

### 3.1 Prototype development

To begin, a prototype of a paper form needs to be developed. Be clear from the outset what information the form is intended to collect and which reporting groups the form is aimed at. This will then help when making decisions, such as the language and questions posed. It may be that you decide to develop more than one form at the prototype stage to compare the merits of each form.

You can design a form by collaborating with NCA's staff or by using external developers. Basing a form on an existing design can be a good starting point, before tailoring it to specific local needs. Using simple computer software, such as Microsoft Word, is a practical and simple way to design a form whilst keeping costs down.

## 3.2 User testing

When developing a new form or making significant updates, it is worth considering user testing. Carefully planned user testing allows you to collect feedback from prospective reporters, which can be immediately addressed in order to improve the form and ensure its success. However, it can be timely and costly to carry out. User testing can be as simple as asking your colleague for a quick check or it can be thoroughly planned testing on a large scale. It is important to decide what works best for your needs, whilst considering the resource you have available and the added value the feedback is likely to provide. For example, a small update to an existing form is less likely to need testing than a brand new form would.

There are a number of decisions to make when designing user testing – namely, how to carry it out, including the user group testing it, timeframes for testing, and how to gather useful feedback.

The form either needs to be distributed to stakeholders who can provide comments from simply looking at it, or you can circulate it to real reporters and see what information is provided to check that the form is filled out well and that there are no areas of confusion. In some countries there may also be specialist companies that can comment on the form's usability.

Identifying appropriate user groups and planning user testing is important to ensure you receive valid feedback, and there are a number of ways to do this.

1. Make use of existing collaborations and engaged stakeholders. This can include asking for feedback from committees, regional centres, members of existing circulation lists, internal staff and even existing reporters, by attaching requests to acknowledgments.
2. Sourcing specific target user groups may be most appropriate; for example, elderly patients or those with visual difficulties. Using existing contacts may again be a valuable way to identify these user groups. It may also be useful to contact health professionals at health centres or hospitals to recruit relevant patients, identify existing patient support groups, and advertise on relevant websites.
3. Feedback from individuals will be invaluable; however, it can also be worth creating a focused working group with a range of stakeholders to partake in group discussions and to help generate ideas for improvements. To identify relevant stakeholders, the same methods discussed above can be used.

4. The next question to ask is how long the user testing should be. It will need to be long enough to allow users time to respond, whilst bearing in mind that timeframes should be as short as possible to limit resource use and enable quick implementation. For example, if users will be contacted by post and the response is received by post, it will be necessary to allow several weeks; however, if a patient group is approached in person, they could be asked to provide feedback by the end of the meeting. It may even be useful to do waves of testing with different user groups, which could require different timelines. For example, start by asking colleagues for feedback to identify initial comments, then roll out to external user groups.
5. Finally, the collection of feedback is vital. A common way of collecting feedback is through written comments using questionnaires. Questionnaires can ask both open and closed questions and should allow the user to provide any comments they feel are relevant. The questionnaire should be easy to fill in and prompt the users to comment on aspects of the design, content and usability. It will also be important to review how the form has been filled in to identify any areas of confusion or where the quality of information provided could be improved.

Once a finalised form has been agreed, it is important to think about promotion of the form; awareness campaigns are discussed in detail in WP4. Additionally, keep in mind the need for continuous improvement. Elements that have not been picked up in user testing may be collected after the form is launched, through spontaneous feedback and coordinated questionnaires. Additionally, updates may be required if legislation changes, so future review should form a part of the whole process.

### Case Study 1. The Maltese Medicines Authority



The Maltese Medicines Authority undertook a review<sup>7</sup> of their reporting forms in response to the 2012 EU legislation changes. They aimed to develop a combined ADR and medication error reporting form and began by reviewing existing forms from other NCAs, as well as forms in health settings to identify strengths and weaknesses that they could learn from. The Maltese Medicines Authority then developed four example case studies to test the new form and took advantage of internal staff to provide initial feedback, which was used to make the first set of improvements. Next, the updated form was distributed to the in-pharmacy department of Malta's General hospital and Malta's Primary Health Care Directorate, and feedback was collected using a form with seven open-ended questions.

The feedback led to the following updates:

- Date fields to prompt three values (day, month and year) to highlight the need for a full date
- Medicine dose field was improved with the addition of frequency and route of administration
- Clearer ADR outcome options were added, per reaction, rather than overall outcome
- Seriousness fields were updated to allow each ADR its own seriousness, rather than only at a case level.

The Maltese Medicines Authority finalised the form and distributed these to stakeholders alongside an awareness campaign to launch the new form.

### Case Study 2. The MHRA Yellow Card Scheme



The Medicines and Healthcare products Regulatory Agency (MHRA) Yellow Card Scheme was launched in 1964 and enabled doctors to report suspected ADRs. This scheme was gradually rolled out to all HCPs, but patients could not report. Therefore, in 2003 a provisional pilot began, which allowed patient reports to be submitted via the United Kingdom (UK) National Health Service helpline, yielding 39 reports over one year. An independent review<sup>8</sup> was published in 2004 and one of the recommendations was that patients should be able to report directly to the MHRA. Following this, a patient reporting working group was set up to help with a pilot, which was launched in early 2005. Paper forms for patients were distributed to 4,000 GP surgeries across the UK and the web-form was updated to allow direct patient reporting.

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<sup>7</sup> Tanti, A, Serracino-Inglott, A and Borg, J.J. Designing a national combined reporting form for adverse drug reactions and medication errors. *Eastern Mediterranean Health Journal*. 2015, 21 (4): 246-255

<sup>8</sup> Report of an independent review of access to the Yellow Card scheme. The Stationary Office. 2004



An evaluation was conducted on the reports received for completeness, causality, whether the ADR was known or labelled in the product information and the word count used to describe the reaction. The evaluation found that, whilst completeness scores were lower for patient reports, no difference in causality assessment or the proportion of unlisted ADRs was seen. It was found that patient's use more words to describe ADRs, which would later be concluded to reveal more information about the impact of ADRs on quality of life. Following this, the pilot was expanded at the end of 2005.

The pilot was run for two years and further evaluation showed that patients reported similar levels of serious reactions and backed up the initial review that reports were less complete, but that there was no difference in causality, or the proportion of unlabelled reactions reported. Patient reporting was subsequently formally launched in 2008 and was accompanied by an awareness campaign.

Once patient reporting had been embedded in the Yellow Card Scheme, a further evaluation was published in 2011<sup>9</sup>. The paper concluded that patient reporting of suspected ADRs had the potential to add value to pharmacovigilance by reporting types of drugs and reactions different from those reported by HCPs; generating new potential signals; and describing suspected ADRs in enough detail to provide useful information on likely causality and impact on patients' lives.

The evaluation also undertook user testing to ensure that the reporting forms met the patient and NCA needs. To achieve this, members of the public in Nottingham, UK, were invited to seven focus groups where views on patient reporting of ADRs were explored. Participants were then observed completing reports for simulated ADR scenarios, detailed information was recorded on their experiences and suggestions for improvements were collated.

Usability testing with 40 participants in the seven focus groups identified several suggestions for enhancing paper reports including:

- Allowing more space for the recording of multiple medications
- Having a larger font size for people with visual impairment
- Redesigning the envelope so that the report fits within it more easily.

The recommendations from the paper were taken on board and the form has since had further updates. Patient reports continue to be a valuable component of pharmacovigilance at the MHRA.

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<sup>9</sup> Avery AJ, et al. Evaluation of patient reporting of adverse drug reactions to the UK 'Yellow Card Scheme': literature review, descriptive and qualitative analyses, and questionnaire surveys. *Health Technol Assess* 2011;15(20):1-234.

### Case Study 3. MHRA review of ADRs in pregnancy



Women taking antiepileptics during pregnancy are known to be at an increased risk of having a child with birth defects, however, following further studies, which indicated a risk of long-term neurodevelopmental effects, the MHRA decided to review ADRs in pregnancy. The review raised concerns that the collection of pregnancy data in spontaneous ADR reports in the UK needed to be improved. Data on ADRs in pregnancy is typically limited due to the ethical issues of recruiting pregnant women for clinical trials and this means many medicines have not been proven as safe in pregnant women. As such, spontaneous ADR reports are a valuable opportunity to gather information.

Representatives from an epilepsy patient support group were identified to help suggest improvements to both the HCP and patient paper and web-forms. Two updates were made to the HCP paper form: the first was the addition of a question in the patient identifiers section to ask 'Is the patient pregnant? Y/N'. Secondly, in the 'Additional relevant information' free text, the wording was amended from:

*For congenital abnormalities please state all other drugs taken during pregnancy and the date of the last menstrual period.*

To:

*For reactions relating to use of a medicine during pregnancy please state all other drugs taken during pregnancy, the last menstrual period, information on previous pregnancies, ultrasound scans, any delivery complications, birth defects or developmental concerns.*

The patient paper form received similar updates. As with the HCP form, a question was added to ask if the patient was pregnant, as well as an update to the medical history, where the wording was amended from:

*Any other relevant information? For example, does the person have any medical conditions or allergies?*

To:

*Any other relevant information? For example, does the patient have any medical conditions or allergies? If the patient is pregnant, please provide date of last menstrual period and as much information as you can about this and any previous pregnancies.*

These updates were successfully implemented to future batches of printed forms and accompanied by a Drug Safety Update<sup>10</sup>, which is the MHRAs monthly newsletter for updated advice on medicines.

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<sup>10</sup> mhra.gov [Online] <https://www.gov.uk/drug-safety-update/yellow-card-update-to-form>



### 3.3 Content of the form

The form must prompt reporters to provide information that is helpful to the NCA for signal detection and assessment. Some information is essential as it is mandatory information for a valid report. Some information is important for the ability to assess the case, such as onset times, whilst other information is additional information that might be helpful, but is not critical to the case, e.g. past drug history. A typical paper form can be split into six distinct sections:

1. Patient Details
2. Suspect Drug(s)
3. Suspect Reaction(s)
4. Other Drug(s)
5. Additional Information
6. Reporter Details.

[Annex 1](#) provides a list of potential fields for a paper form, including whether they are mandatory and what the value of requesting the information is. Unless the right questions are asked, the information necessary to perform signal detection is unlikely to be shared by the reporter.

It is important to highlight the information that is essential to receive in some way. Whilst provision of information cannot be enforced for paper reports, having a mechanism to highlight mandatory fields, e.g. using an asterisk, can help the reporter to prioritise these sections. An example from the MHRA is shown below.

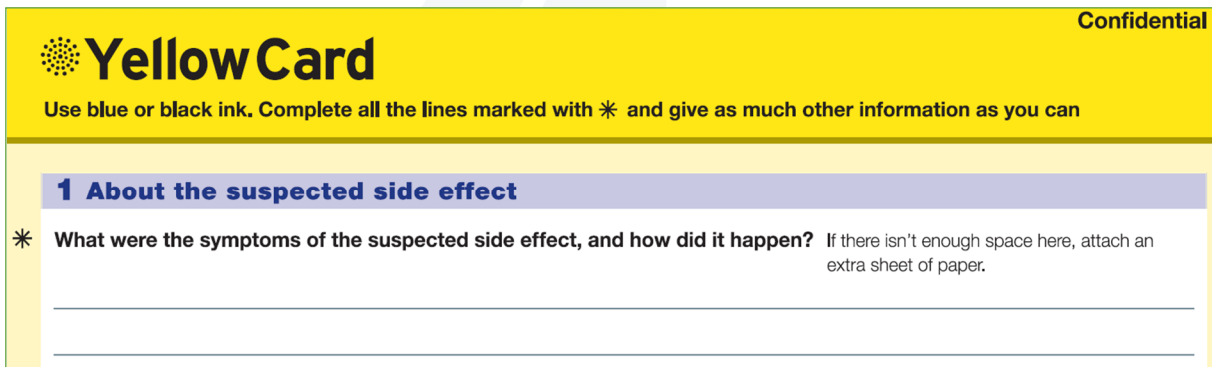


Figure 1. Asterisk used by the MHRA on a patient paper form to highlight mandatory fields

It can also be useful to include short explanations of the fields or provide examples where confusion may arise, such as in the example below from the MHRA. NCAs are likely to want full dosage details, so the use of an example will prompt the reporter to provide this level of detail.

<b>Name of the medicine</b>
<b>Dosage</b> (for example, one 250 mg tablet, twice a day)

Figure 2. The MHRA patient paper form showing dosing example

To ensure reporters are comfortable providing personal information, it can be worth adding a line to explain that all details remain confidential. Additionally, if collecting information on medication errors, then a sentence explaining that no disciplinary action will be initiated on the basis of this report can build trust and help gather all the relevant information. The Maltese Medicines Authority have a system which destroys reporter details after submission to EudraVigilance (EV) when reporting a medication error<sup>11</sup>. Their form also includes a statement which says:

*'IMPORTANT: The submission of a report does not constitute an admission that the patient, medical personnel, user facility, importer, distributor, manufacturer or the medicine itself caused or contributed to the event.'*

And in the reporter details section they state that:

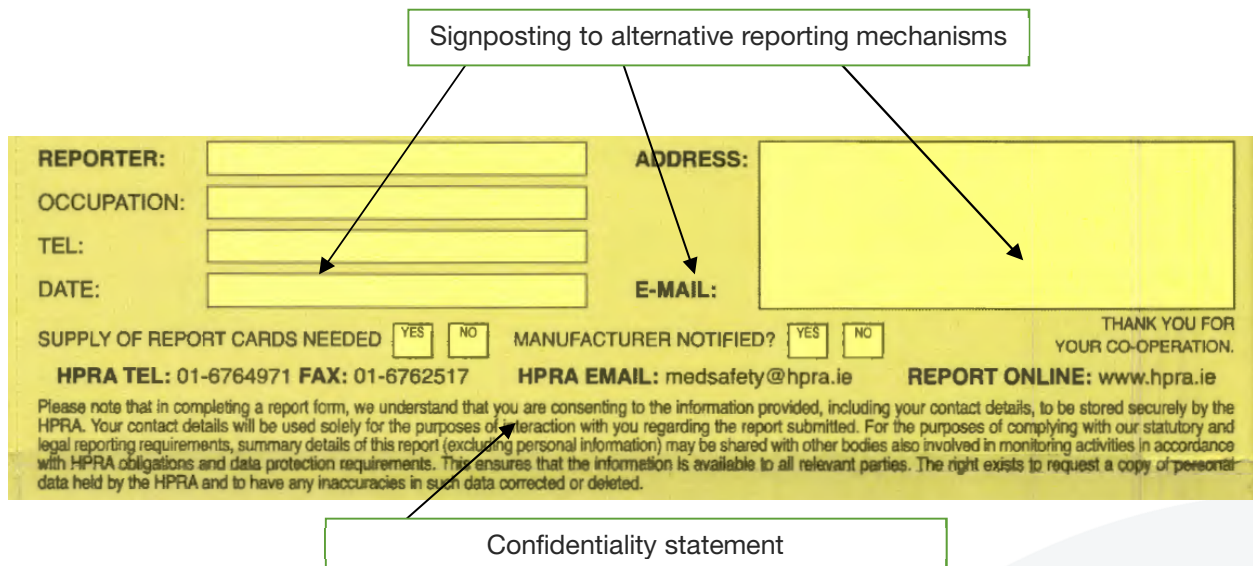
*'Details will be destroyed following transmission to the EU central side effect database EudraVigilance.'*

Reporting of medication errors is discussed in more detail in a separate WP4 document.

It is worth taking the opportunity to advertise alternative reporting mechanisms briefly, for example, providing the URL link to an online reporting website can prompt reporters to submit electronically, which can be easier. The Irish Health Products Regulatory Authority (HPRA) provides alternative ways to contact and report to the HPRA at the bottom of their form and also includes a confidentiality statement.

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<sup>11</sup> A.Tanti, A. Serracino-Inglott and J.J. Borg Designing a national combined reporting form for adverse drug reactions and medication errors, Eastern Mediterranean Health Journal Vol. 21 No. 4, 2015



Signposting to alternative reporting mechanisms

REPORTER:   
OCCUPATION:   
TEL:   
DATE:

ADDRESS:   
E-MAIL:

SUPPLY OF REPORT CARDS NEEDED  YES  NO MANUFACTURER NOTIFIED?  YES  NO

HPRA TEL: 01-6764971 FAX: 01-6762517 HPRA EMAIL: [medsafety@hpra.ie](mailto:medsafety@hpra.ie) REPORT ONLINE: [www.hpra.ie](http://www.hpra.ie)

THANK YOU FOR YOUR CO-OPERATION.

Please note that in completing a report form, we understand that you are consenting to the information provided, including your contact details, to be stored securely by the HPRRA. Your contact details will be used solely for the purposes of interaction with you regarding the report submitted. For the purposes of complying with our statutory and legal reporting requirements, summary details of this report (excluding personal information) may be shared with other bodies also involved in monitoring activities in accordance with HPRRA obligations and data protection requirements. This ensures that the information is available to all relevant parties. The right exists to request a copy of personal data held by the HPRRA and to have any inaccuracies in such data corrected or deleted.

Confidentiality statement

Figure 3. The HPRRA reporting form with signposting to alternative reporting mechanisms and a confidentiality statement

Additional features to consider are:

- Include the return address
- Include a simple 'Thank you for taking the time to complete this form'
- Where necessary, develop the form in multiple languages.

### 3.4 Layout and design

The layout and design of the form needs to be simple for the user and easy to navigate. Presenting the form in sections with numbering, headings or by drawing lines to break sections up can make the form look clearer and less arduous. It is important to allow appropriate space for each question relating to the length of the answer expected. If the response to a question is expected to be short, e.g. patient age, then leaving just a small space to fill in will be fine. If more detail is required, e.g. reaction narrative, then leaving a much bigger space will indicate that more information is requested and it will allow the reporter to write everything down. There are also choices the reporter can be required to make from a pre-fixed list, e.g. Council for International Organisations of Medical Sciences (CIOMS) seriousness; in these instances it can be best to use tick boxes or request to have the answer encircled.

Fonts and use of colour can help to make the form more visually appealing. Use a font that is clear to read, such as Arial, and ensure the font size is readable, e.g. 12-point. The size and font is an aspect that can be addressed in user testing. Having the ability to print forms in bigger font sizes is an advantage for visually impaired reporters.

Printing the form on coloured paper or using coloured ink can help the form to stand out as well as being used to emphasise aspects of the form, for example essential fields. Additionally, having the NCA logo and branding can provide confidence to the reporter of the form's authenticity. The use of colours will need to be carefully considered, as this will add expense to the form production.

### 3.5 Language used

The questions posed must be clear and simple to understand to ensure collection of high-quality information and to prevent confusion and frustration to the reporter. Consider the audience that will be using the form and use language that will be familiar to them. For example, asking for the 'drug indication' will be fine for a HCP, but 'why were you taking the medicine?' may be more easily understood by patients. Limit the use of jargon and abbreviations unless clearly explained on the form and be succinct with sentences; too much text can be off-putting.

### 3.6 Types of form

Depending on NCA requirements and the available resources, one or more forms can be developed. A single paper form design can be sufficient, however it is worth thinking about developing multiple forms for different target users and the collection of different types of ADRs. The scope of an ADR has expanded in recent years and is now defined as 'a response to a medicinal product which is noxious and unintended' and can arise from:

- The use of a medicinal product within the terms of the marketing authorisation
- Use outside the terms of the marketing authorisation, including overdose, off-label use, misuse, abuse and medication errors
- Occupational exposure.

As such, having a 'one size fits all' paper form may not be optimal, as it can be difficult to include requirements for all scenarios. If using multiple forms then it is important to make sure that each form is distinctly different and that the aim of each is clear by varying the way the form looks and what it includes. If reporters are confused about which form to use and when, or what to do if there is overlap in forms, then this can put people off reporting and so should be avoided. With this in mind, it is likely that you will benefit from a small number of well-developed tailored forms rather than countless forms for multiple different scenarios.

There are advantages and weaknesses to both approaches, which are summarised in the **Table 1** below.

**Table 1. Advantages and weaknesses of generalised and tailored forms**

Form type	Advantages	Weaknesses
Generalised form	<ul style="list-style-type: none"> <li>• Accessible to all</li> <li>• Cheaper and quicker to maintain and develop</li> </ul>	<ul style="list-style-type: none"> <li>• The same authority might not be responsible for all reports, e.g. medication errors may be handled differently</li> </ul>
Tailored form	<ul style="list-style-type: none"> <li>• Language can be tailored to the target audience, i.e. more complex language for HCPs than patients</li> <li>• Questions can be more specific to different scenarios, e.g. vaccines</li> </ul>	<ul style="list-style-type: none"> <li>• More time consuming and expensive to produce multiple forms initially</li> <li>• Possible reporter confusion about which form to report with</li> </ul>

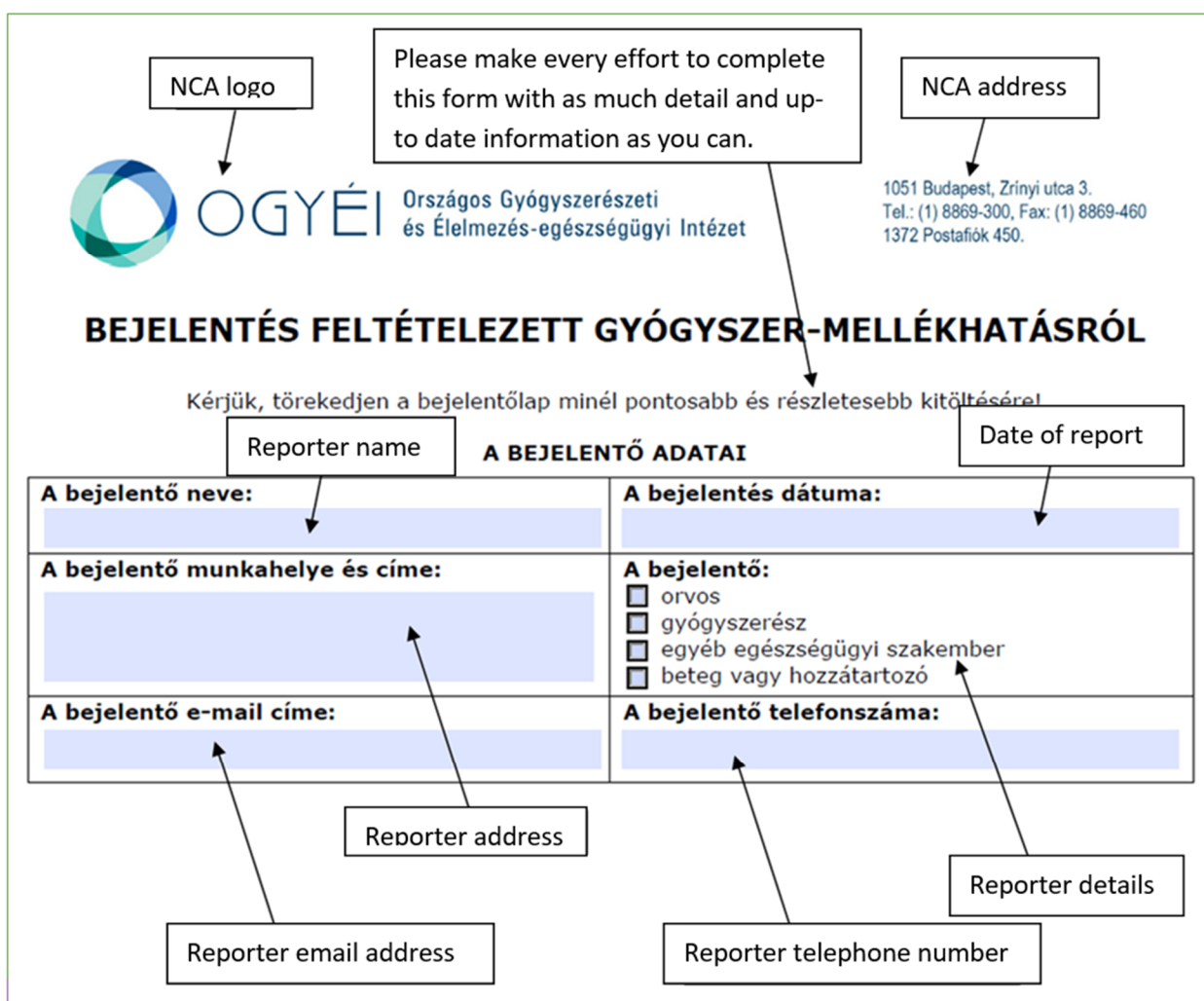
Below are examples of different forms – those that are generalised, tailored patient forms and HCP forms, as well as an example specific to vaccines.

## Generalised forms

The Hungarian National Institute of Pharmacy and Nutrition (OGYÉI) have a combined (for HCPs and patients) two-page A4 reporting form using clear font. Their form is clearly sectioned and makes use of check boxes and free text options. Their logo and address are clearly provided to the reporter.

They highlight the need for collection of batch information and include a line to ask:

*'In case of biological product, please always indicate the brand name of the drug as well as the batch number.'*



Please make every effort to complete this form with as much detail and up-to-date information as you can.

**NCA logo** → OGYÉI Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet

**NCA address** → 1051 Budapest, Zrínyi utca 3.  
Tel.: (1) 8869-300, Fax: (1) 8869-460  
1372 Postafiók 450.

**BEJELENTÉS FELTÉTELEZETT GYÓGYSZER-MELLÉKHATÁSRÓL**

Kérjük, törekedjen a bejelentőlap minél pontosabb és részletesebb kitöltésére!

**Reporter name** → A bejelentő neve:

**Date of report** → A bejelentés dátuma:

**Reporter address** → A bejelentő munkahelye és címe:

**Reporter email address** → A bejelentő e-mail címe:

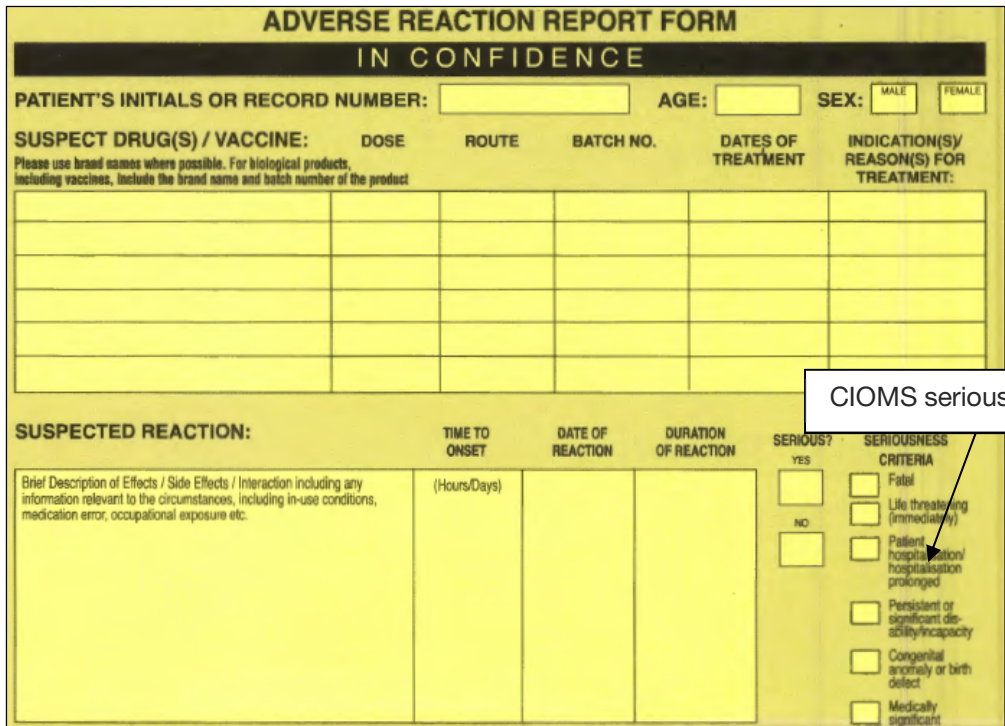
**Reporter details** → A bejelentő:  orvos,  gyógyszerész,  egyéb egészségügyi szakember,  beteg vagy hozzátartozó

**Reporter telephone number** → A bejelentő telefonszáma:

Figure 4. The OGYÉI combined paper reporting form



The HPRA have a combined paper reporting form of single-sided A4, which is clearly sectioned and prompts for important pieces of information, such as CIOMS seriousness.



**ADVERSE REACTION REPORT FORM**  
**IN CONFIDENCE**

PATIENT'S INITIALS OR RECORD NUMBER:  AGE:  SEX:  MALE  FEMALE

SUSPECT DRUG(S) / VACCINE: DOSE ROUTE BATCH NO. DATES OF TREATMENT INDICATION(S)/ REASON(S) FOR TREATMENT:

Please use brand names where possible. For biological products, including vaccines, include the brand name and batch number of the product

SUSPECTED REACTION:	TIME TO ONSET (Hours/Days)	DATE OF REACTION	DURATION OF REACTION	SERIOUS?	SERIOUSNESS CRITERIA
Brief Description of Effects / Side Effects / Interaction including any information relevant to the circumstances, including in-use conditions, medication error, occupational exposure etc.				YES <input type="checkbox"/>	<input type="checkbox"/> Fatal
				NO <input type="checkbox"/>	<input type="checkbox"/> Life threatening (immediately)
					<input type="checkbox"/> Patient hospitalisation/hospitalisation prolonged
					<input type="checkbox"/> Persistent or significant disability/incapacity
					<input type="checkbox"/> Congenital anomaly or birth defect
					<input type="checkbox"/> Medically significant

CIOMS seriousness criteria

Figure 5. The HPRA combined reporting form

The HPRA have a downloadable paper form, as well as one which is included in their Irish Medicine Formulary and prescribing guides, which emphasises the need for receiving batch details for certain medicines by having a footer to say:

*'Please use brand names where possible. Please note that for biological products, including vaccines, it is essential to include the brand name and batch number of the product.'*

### Reporter specific form: HCP form

The MHRA have a HCP form, which is available in the UK prescribing book, the British National Formulary (BNF), and is also available to download. The form is printed on yellow paper and is double-sided A5. The form benefits from a well-structured design and directs reporters to further information, such as 'Drug Safety Update' bulletins and alternative ways of reporting.

Signposting to alternative ways of reporting

BNF In Confidence

**YellowCard**  
COMMISSION ON HUMAN MEDICINES (CHM)

It's easiest to report online at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

**MHRA**  
Regulating Medicines and Medical Devices

**SUSPECTED ADVERSE DRUG REACTIONS**

If you suspect an adverse reaction may be related to one or more drugs/vaccines/complementary remedies, please complete this Yellow Card. See 'Adverse reactions to drugs' section in BNF or [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk) for guidance. Do not be put off reporting because some details are not known.

**PATIENT DETAILS** Patient Initials: \_\_\_\_\_ Sex: M / F Is the patient pregnant? Y / N Ethnicity: \_\_\_\_\_  
Age (at time of reaction): \_\_\_\_\_ Weight (kg): \_\_\_\_\_ Identification number (e.g. Practice or Hospital Ref): \_\_\_\_\_

**SUSPECTED DRUG(S)/VACCINE(S)**

Drug/Vaccine (Brand if known)	Batch	Route	Dosage	Date started	Date stopped	Prescribed for

**SUSPECTED REACTION(S)** Please describe the reaction(s) and any treatment given: \_\_\_\_\_

Date reaction(s) started: \_\_\_\_\_ Date reaction(s) stopped: \_\_\_\_\_

Do you consider the reactions to be serious? Yes / No

If yes, please indicate why the reaction is considered to be serious (please tick all that apply):

Patient died due to reaction  Involved or prolonged inpatient hospitalisation  
 Life threatening  Involved persistent or significant disability or incapacity  
 Congenital abnormality  Medically significant; please give details: \_\_\_\_\_

If the reactions were not serious according to the categories above, how bad was the suspected reaction?  
 Mild  Unpleasant, but did not affect everyday activities  Bad enough to affect everyday activities

**Outcome**  
Recovered   
Recovering   
Continuing   
Other

Figure 6. The MHRA HCP paper form, page 1

It's easiest to report online at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

**OTHER DRUG(S) (including self-medication and complementary remedies)**

Did the patient take any other medicines/vaccines/complementary remedies in the last 3 months prior to the reaction? Yes / No

If yes, please give the following information if known:

Drug/Vaccine (Brand if known)	Batch	Route	Dosage	Date started	Date stopped	Prescribed for

Additional relevant information e.g. medical history, test results, known allergies, rechallenge (if performed). For reactions relating to use of a medicine during pregnancy please state all other drugs taken during pregnancy, the last menstrual period, information on previous pregnancies, ultrasound scans, any delivery complications, birth defects or developmental concerns.

Please list any medicines obtained from the internet: \_\_\_\_\_

REPORTER DETAILS	CLINICIAN (if not the reporter)
Name and Professional Address: _____	Name and Professional Address: _____
Postcode: _____ Tel No: _____	Postcode: _____ Tel No: _____
Email: _____	Email: _____
Speciality: _____	Speciality: _____
Signature: _____ Date: _____	Date: _____

Information on adverse drug reactions received by the MHRA can be downloaded at [www.mhra.gov.uk/daps](http://www.mhra.gov.uk/daps)  
Stay up-to-date on the latest advice for the safe use of medicines with our monthly bulletin *Drug Safety Update*, at [www.mhra.gov.uk/drugsafetyupdate](http://www.mhra.gov.uk/drugsafetyupdate)  
Please attach additional pages if necessary. Send to: FREEPOST YELLOW CARD (no other address details required)

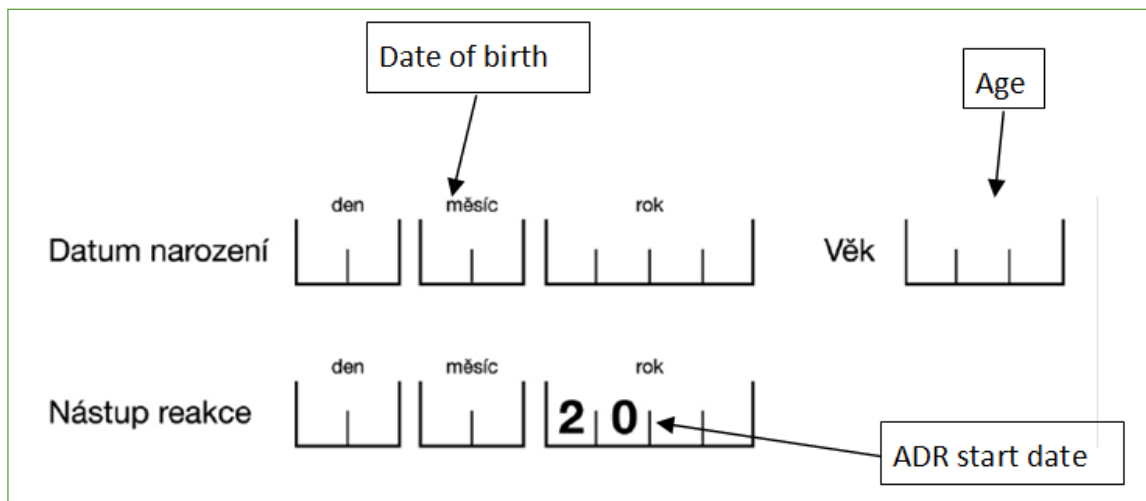
Signposting to further sources of information

Figure 7. The MHRA HCP paper form, page 2



The Czech Republic State Institute For Drug Control (SUKL) have a double-sided A4 form. The first side has the reporting form and on the back is supporting guidance.

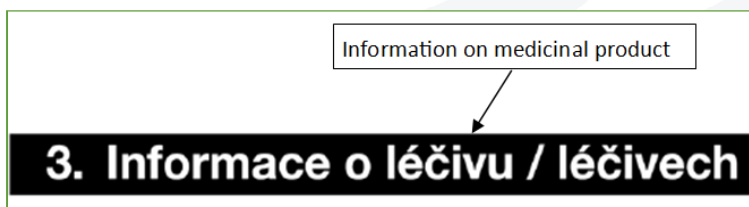
Where dates are requested they provide structured date formats, which guides the reporter on the information requested.



The diagram illustrates the structured date fields on the SUKL form. It shows three main sections: 'Datum narození' (Date of birth), 'Věk' (Age), and 'Nástup reakce' (Onset of reaction). Each section has a corresponding label in a box with an arrow pointing to the field. 'Datum narození' is split into 'den' (day), 'měsíc' (month), and 'rok' (year). 'Věk' is a single field. 'Nástup reakce' is split into 'den', 'měsíc', and 'rok', with the 'rok' field containing the value '20'. A label 'ADR start date' points to the 'rok' field of 'Nástup reakce'.

Figure 8. The SUKL form with clear structure for requesting information

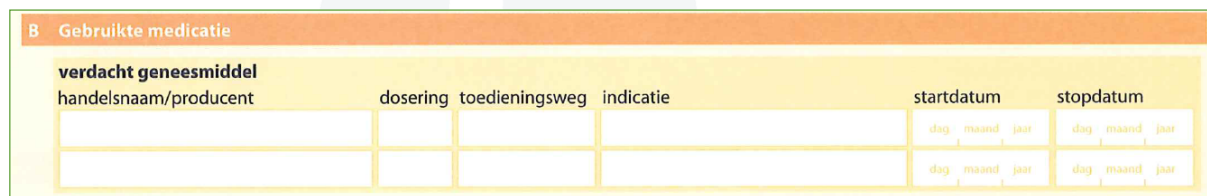
Sections on the form are clearly identified by numbering and labelling.



The diagram shows a section of the SUKL form with a black header bar containing the text '3. Informace o léčivu / léčivech'. Above this bar is a label 'Information on medicinal product' with an arrow pointing to the header.

Figure 9. The SUKL form with clear sections

The Netherlands Pharmacovigilance Centre Lareb have a combined double-sided A4 form. The form also successfully creates clear sections, with spaces to write the answer that indicate the length of the answer required.




The diagram shows a table from the Lareb form titled 'B Gebruikte medicatie'. The table has six columns: 'verdacht geneesmiddel', 'dosering', 'toedieningsweg', 'indicatie', 'startdatum', and 'stopdatum'. The 'startdatum' and 'stopdatum' columns are further divided into 'dag', 'maand', and 'jaar' sub-columns. The 'verdacht geneesmiddel' column is further divided into 'handelsnaam/producent'.

B Gebruikte medicatie					
verdacht geneesmiddel					
handelsnaam/producent	dosering	toedieningsweg	indicatie	startdatum	stopdatum
				dag maand jaar	dag maand jaar
				dag maand jaar	dag maand jaar

Figure 10. The Lareb form with clear structure

### Reporter specific form: Patient form

The MHRA have a patient form that is available as a booklet, which is distributed to patients and is also available to download. The form is printed with coloured ink on white paper and is double-sided A4.


**Confidential**

Use blue or black ink. Complete all the lines marked with \* and give as much other information as you can

#### 1 About the suspected side effect

\* **What were the symptoms of the suspected side effect, and how did it happen?** If there isn't enough space here, attach an extra sheet of paper.

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**How bad was the suspected side effect?** Tick the box that best describes how bad the symptoms were.

\*  Mild    Unpleasant, but did not affect everyday activities    Bad enough to affect everyday activities    Bad enough to see doctor

Bad enough to be admitted to hospital    Caused very serious illness    Caused death    Other \_\_\_\_\_

**When did the side effect start?**

\_\_\_\_\_

**How is the person feeling now?** Tick the box that best describes whether the person still has symptoms of the suspected side effect.

\*  Better (no more symptoms)    Getting better    Still has symptoms    More seriously ill    Died    Other

**Can you give any more details?** For example, did the person take or receive any other treatment for the symptoms? Did they stop taking the medicine as a result of the side effect?

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

#### 2 About the person who had the suspected side effect

Make sure you have completed all the lines marked \*

Please turn over →

Mandatory information is highlighted

Figure 11. The MHRA patient form, page 1

### 3 About the medicine(s) which might have caused the side effect

Give details of the medicine you suspect of causing the side effect.

\* **Name of the medicine** \_\_\_\_\_  prescription  bought in pharmacy  bought elsewhere  
 \_\_\_\_\_  bought on the internet  
Dosage (for example, one 250 mg tablet, twice a day)

What was it taken for?  
 \_\_\_\_\_

Start date: \_\_\_\_\_ End date: \_\_\_\_\_ Did you stop because of side effects?  Yes  No

---

If you (or the person you're reporting for) were taking any other medicine at the same time (which might have caused an interaction), give details of it. If you need to give details of more than one other medicine, attach an extra sheet of paper.

**Name of other medicine** \_\_\_\_\_  prescription  bought in pharmacy  bought elsewhere  
 \_\_\_\_\_  bought on the internet  
Dosage (for example, one 250 mg tablet, twice a day)

What was it taken for?  
 \_\_\_\_\_

---

Do you think this medicine might also have caused the side effect?  Yes  No  Possibly \_\_\_\_\_

Start date: \_\_\_\_\_ End date: \_\_\_\_\_ Did you stop because of side effects?  Yes  No

Have you taken any other medicines or herbal remedies (as well as the above) within the last 3 months?  Yes  No

### 4 About your doctor (optional)

**Would you like a copy of this report to be sent to your doctor?**  
 Yes  No **If Yes, give the doctor's name and address.**

Doctor's name \_\_\_\_\_

**If you want us to send a copy of this report to any other healthcare professional, attach a separate sheet with their contact details.**

Address \_\_\_\_\_

**If we need more medical information (such as test results), do we have your permission to contact your doctor directly for it?**  
 Yes  No

Postcode \_\_\_\_\_

---

### 5 About you – the person making the report

**We need contact details** – please supply a full postal address, even if you prefer not to give a phone number or email address.

\* Title \_\_\_\_\_ First name or initials \_\_\_\_\_ Family name \_\_\_\_\_

\* Address \_\_\_\_\_

\* \_\_\_\_\_ Postcode \_\_\_\_\_

Telephone number \_\_\_\_\_ Email address \_\_\_\_\_

**Please sign and date this form**

I agree that the Medicines and Healthcare products Regulatory Agency (MHRA) can contact me to discuss the suspected side effect, and to ask for more information that might help understanding of the case.

\* Signed \_\_\_\_\_ Date \_\_\_\_\_

Please return this form in the envelope provided to: FREEPOST YELLOW CARD. (No other address details are required) © Crown Copyright 2015

Option to contact the patient's doctor is provided

Figure 12. The MHRA patient form, page 2

### Vaccine specific form

The Polish Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL) have a form that can be used to report all ADRs, as well as two specialised vaccine forms. The first vaccine form is aimed at patients that receive the Bacillus Calmette–Guérin (BCG) vaccine; the second is used for all other vaccines. The form differs to generalised ADR paper forms for a number of reasons. Rather than using free text to capture the suspect vaccine and reaction, there are check boxes for the reporter to use which suggest likely vaccines and reactions a patient might experience. Using check boxes can help the reporter to provide the necessary information, but the option to write free text is not lost, so reporters can still report any event they believe to be related to the vaccination.

Reporters are also asked whether the injection was given correctly, where applicable, as well as if anyone else who was vaccinated also experienced ADRs. These are in addition to more common inclusions on the form, such as dates, batch numbers and outcomes.

**III. INFORMACJE O SZCZEPIENIU**

Szczepionka podejrzana o wywołanie odczynu:  Błonica     Teżec     Krztusiec     OPV     IPV  
 Odra     Świnka     Różyczka     wzw A     wzw B     Grypa     Inna (jaka?).....

Data szczepienia / /  Godz. :  Data wystąpienia odczynu / /  Godz. :

**IV. NIEPOŻĄDANY ODCZYN PO SZCZEPIENIACH INNYCH NIŻ BCG**

**Reakcja miejscowa**

Nasilony odczyn w miejscu wstrzyknięcia →  O średnicy 3 – 5 cm     Wykraczający poza najbliższy staw  
(obrzęk, zaczerwienienie i bolesność)     O średnicy 6 – 9 cm     Utrzymujący się ponad 3 dni  
 O średnicy większej niż 10 cm

Ropień w miejscu wstrzyknięcia →  Jalowy     Bakteryjny. Wynik posiewu.....

Bolesność i powiększenie regionalnych węzłów chłonnych.

For local reactions, how large was the affected area?

Which vaccine did the patient receive?

Figure 13. The URPL vaccine paper reporting form

## 4. Guidance, background and supplementary information

Guidance, background and supplementary information, which include texts beyond the minimum requirements for a basic form, are important considerations. Additional explanatory information can be included in the main body of a paper form, so long as it is succinct; signposting to additional information can also be included on the form. Having separate background or supplementary information can be useful for reporters, both in understanding the information to provide, as well as to help engagement with them by explaining the pharmacovigilance process. It is possible, as seen with the SUKL form, to have one side of a form for reporting with the other side being used to provide additional information.

Brief guidance on the form itself can be a useful way of ensuring high-quality information is collected. It needs to be short and clear and, whilst it takes up valuable space, it can be beneficial.

A separate document or a booklet format for providing in-depth details of the pharmacovigilance process and the work of NCAs is helpful. The level of detail provided needs to be considered, sometimes a brief paragraph may suffice, or alternatively a more in-depth discussion may be preferable for different needs. Consider the audience and the purpose of the background and supplementary information to pitch it at the right level.

An important consideration is where this information will be held. If printing out, then there will be limitations on the length, and as such the content and level of detail, whereas, if hosting on a website, this can be as detailed and long as necessary. Details will vary between NCAs, however, below is a suggestion of areas to think about including.

### 4.1 Introduction on why to report suspected ADRs

Providing the reporter with an overview of why licenced medicines can cause side effects, and why these are not always known when a product is initially marketed can help the person to be more understanding of the process.

Explaining the value of spontaneous reports is critical to their engagement and willingness to submit a report; this is particularly important in countries where HCPs are not mandated to report. This can be attempted by explaining the impact of reports on public health with emphasis on the fact that one report can make all the difference. Providing examples of previous signals can add additional impact to the message.

## 4.2 What to report

Clarity regarding what to report can help persuade people who are unsure of their suspicions, as well as focus reporter efforts on the more critical ADRs, for example, those seen in additional monitoring products or in special populations, such as elderly patients. It can also be helpful to explain if it is possible to report on behalf of others, such as for carers.

## 4.3 How reports are used

The pharmacovigilance process is complex and, for many outside of the regulatory field, the work we do is not well known. A simplified description of the pharmacovigilance process, or even a visual aid, for example a flow chart of a report such as theirs, can help to explain the work and help engagement.

This section can include the process of receiving reports and entering them into a database, through to signal detection and the regulatory actions that can be made.

## 4.4 Who to report to

In many countries awareness of the reporting schemes, even amongst HCPs, is low, so background information on who the NCA are can be helpful, including contact details to point them in the right direction for further information.

## 4.5 Methods of reporting

There are several possible reporting methods and paper is just one; providing a range of ways to report will increase access to those that have a preferred method or can't use all, for example those without access to computers may rely on phone or paper reporting.

Summarise the reporting mechanisms available in your NCA, including how to access each method – for example, where to pick up or download a paper form, url links to an online reporting website, contact numbers to report by phone and links to download mobile apps. If clinical systems are integrated into NCA databases, this can also be discussed, even if this reporting method is not available to everyone it is interesting to know they exist.

## 4.6 How to complete a form

Once the reporter has made the decision to report it may be helpful to explain what information is useful to receive. The fields present on the paper form will guide the reporter, but this additional information can place emphasis on the most important details.

The paper form should be designed to be intuitive to a user, but there might still be areas that could benefit from some extra explanation. One approach would be to discuss each of the sections in the form and explain what should be included in each.

Guidance on how to fill in a form can also be delivered with a detailed walkthrough with hints and tips provided. This can be particularly useful to patients; for example, explaining where a patient can find the batch number on their medicine might help them to locate it and provide this information. Using annotated pictures of the report could be useful as a visual aid to help understanding.

## 4.7 Medical advice

NCA's don't typically provide individual medical guidance or advice to patients or HCPs, but, since the reporters are telling us about suspected ADRs to medicines, it is inevitable that they may also be looking for help. Directing reporters to where they can access medical advice is both helpful to them and avoids frustration if they have expectations that the NCA can help.

Medical advice may come from emergency and patient advice helplines, reputable websites, as well as from pharmacists and other HCPs. It is important to include the contact details, where available.

## 4.8 Links to further information

Supplementary information may not provide all information that a reporter is interested in and so it can be helpful to signpost the reporter to further documents or websites, including the NCA's homepage, which can provide additional information.

These may include links to:

- National health services
- Additional information on NCA websites, e.g. NCA literature, newsletters
- Bulletins
- How to sign up to distribution lists for alerts, where available
- The European Medicines Agency (EMA).

It will be important for each NCA to consider what is important for them to provide and to develop tailored guidance, as necessary. For example, SUKL include supplementary information on the back of their A4 paper form that includes the following sections:

- What to report
- Definitions of ADRs, seriousness criteria and summary of product characteristics (SPCs)
- How to report, including alternative methods such as online and by phone
- What happens to your report, including pharmacovigilance description, signal definition and what happens when a new issue arises
- Confirmation of confidentiality.



## 5. Availability

Ensuring potential reporters have easy access to a paper form is clearly a crucial component for success. There are a number of ways to make forms available and it is important that a range of approaches are used to reach out to various target groups. A number of options to consider are listed in Table 2 below.

Table 2. Ways to distribute paper reporting forms

HCPs	Patients	Both HCPs and patients
<ul style="list-style-type: none"> <li>• Distribution to surgeries, hospitals and pharmacies</li> <li>• Provision in specialist publications</li> <li>• Along with bulletins</li> <li>• Inclusion in national formularies and prescribing handbooks</li> </ul>	<ul style="list-style-type: none"> <li>• Availability in healthcare waiting rooms</li> <li>• Handouts at patient support groups</li> <li>• Attached to patient-focused leaflets</li> </ul>	<ul style="list-style-type: none"> <li>• Downloadable online</li> <li>• NCA can send reports on request, including in a larger font size if available</li> <li>• Handouts at lectures/talks</li> <li>• Distribution via regional centres</li> <li>• Attached with acknowledgements</li> </ul>

To remove barriers to submitting paper forms, several NCAs provide a freepost envelope to reporters and this is a beneficial incentive, where funds allow. Some NCAs even print their forms on paper with sticky 'gum edge' that, once folded, becomes the envelope, which makes it very easy to send a report.

## 6. Feedback

Reporters understandably want to be acknowledged when reporting, to feel valued, to be confident the report has been received and to learn more about the work of the NCA. Feedback to reporters is discussed in detail in WP4, Topic 2. There is an opportunity on the reporting form to set reporters expectations, as well as to seek permission for further contact.

Patient reporting has been shown to be valuable in the signal detection process<sup>12</sup> and it is important to remove the barriers that might dissuade patients from reporting. One reason patients may be dissuaded is that further contact may or may not be welcomed. By respectfully asking patients for their permission, they have the opportunity to make this decision. Permissions that may be sought include further contact for follow-up questions, as well as options to acknowledge and follow up with their doctor. Asking for permissions for future contact will forewarn the patient that they may receive a follow-up, as well as help the NCA gain further information on a suspected ADR.

It may be prudent to add a sentence to either explain reasons not to expect personal contact, where this is not currently provided, or else to give a timeframe within which reporters can expect to receive acknowledgements and feedback, where provided.

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<sup>12</sup> Avery AJ, et al. Evaluation of patient reporting of adverse drug reactions to the UK 'Yellow Card Scheme': literature review, descriptive and qualitative analyses, and questionnaire surveys. *Health Technol Assess* 2011;15(20):1-234.

## 7. Conclusions

SCOPE WP4 has seen that most countries use, and intend to continue using, paper reporting forms as a method for receiving spontaneous ADR reports. Well-designed paper forms contribute to NCA and international efforts to collect high-quality data on suspected adverse drug reactions, in order to be able to perform signal detection on these reports and ultimately protect public health. Developing a high-quality form is therefore an important aspect of successful pharmacovigilance.

Paper forms have been used for a long time, pre-dating more sophisticated electronic systems, and as such have often undergone a number of iterations to arrive at the forms used today. Updates have been made following stakeholder feedback and changes to NCA processes, as well as in response to legislation changes, and this highlights the need for NCAs to review forms on an ongoing basis.

A perfect paper form for all NCAs is not possible due to local differences, such as language, different target user groups and also because a number of variations can produce an effective form. This guidance provides points to consider when developing new or updated forms, based on the strengths of existing NCA forms, which will help to ensure that future forms continue to meet user needs.

## Annex 1. Fields to include on a paper form

### Essential fields to include on a paper form

Section	Field/Question	Mandatory for a valid report?	Value of the question	Suggested field format
Patient	Patient initials	Yes, or else another patient identifier	This is a component of a valid report and also aids duplicate detection.	Free text
Patient	Identification number	Yes, or else another patient identifier	This is a component of a valid report and also aids duplicate detection.	Free text
Patient	Patient age/Date of birth	Yes, or else another patient identifier	Aids causality assessment. Age can help us understand the way the drug may affect the patient; for example, elderly patients may have reduced renal function, which affects the way a drug is excreted. Not all NCAs can legally store date of birth.	Free text or structured free text, e.g. ‘_/_/’
Patient	Patient sex	Yes, or else another patient identifier	Aids causality assessment. Sex can affect the way a drug works and also allows us to make some assumptions on patient characteristics when assessing reports.	Tick box/circled answer
Reaction	Reaction	Yes	Essential information.	Free text
Suspect Drug	Drug name	Yes	Essential information. For targeted forms, such as biologicals or vaccines, this should be accompanied by a request for brand name and batch number.	Free text

Section	Field/Question	Mandatory for a valid report?	Value of the question	Suggested field format
Reporter	Reporter name	Yes – One or more identifiable reporter detail required, characterised by qualification, name, initials or address.	Essential information.	Free text
Reporter	Reporter address, including first line of address, city, state/province and postcode.	Yes – One or more identifiable reporter detail required, characterised by qualification, name, initials or address.	Allows follow up to be requested.	Free text
Reporter	Other reporter contact details – phone number, email address etc.	Yes – One or more identifiable reporter detail required, characterised by qualification, name, initials or address.	Allows follow up to be requested.	Free text
Reporter	Reporter qualification	Yes – One or more identifiable reporter detail required, characterised by qualification, name, initials or address.	Essential information. Helps when considering the strength of the report details, particularly when diagnoses are made.	Free text

### Recommended fields to include on a paper form

Section	Field/Question	Mandatory for a valid report?	Value of the question	Suggested field format
Administrative and identification information	Date report sent	No	Additional information useful for audit tracking.	Structured free text, e.g. ‘_/_/’
Patient	Patient weight	No	Aids causality assessment. A patient’s weight can affect the way a drug works; additionally weight can indicate potential comorbidities.	Free text
Patient	Patient height	No	Aids causality assessment. Helpful to understanding a patient’s body mass index along with weight.	Free text
Reaction	Seriousness of reactions using CIOMS	No	Provides the reporters view on the impact of the ADR. Some NCAs word this differently for consumer reports.	Tick box/circled answer
Reaction	Reaction start and stop date	No	Aids causality assessment. Allows onset times, durations and biological plausibility to be considered.	Structured free text, e.g. ‘_/_/’
Reaction	Reaction outcome	No	Aids causality assessment. Allows us to assess the impact of the ADR and can enable us to consider rechallenge/dechallenge outcomes.	Tick box/circled answer
Suspect Drug	Suspect drug Batch/lot number	No	Requesting this information is required in legislation for biologicals and vaccines. Batch numbers allow variations in products and batch quality issues to be identified.	Free text
Suspect Drug	Suspect drug dose	No	Aids causality assessment. Dosage enables dose dependent ADRs to be assessed, in some instances this can also allow assumptions regarding the indication or severity of the indication to be made.	Free text

Section	Field/Question	Mandatory for a valid report?	Value of the question	Suggested field format
Suspect Drug	Suspect drug route of administration	No	Aids causality assessment. Drug route of administration affects the action and absorption of the active substance. E.g. topical application of a cream will have lower systemic absorption than an oral tablet.	Free text
Suspect Drug	Suspect drug indication	No	Aids causality assessment. Allows us to understand the patient characteristics and make inferences, particularly important when a drug has multiple indications.	Free text
Suspect Drug	Suspect drug start and stop date	No	Aids causality assessment. Allows onset times, durations and biological plausibility to be considered.	Structured free text, e.g. ‘_/_/_'
Suspect Drug	Action taken with suspect drug	No	Aids causality assessment. All E2B values don't need to be provided, e.g. 'Did you stop the drug due to the reaction' 'Yes' or 'No'.	Tick box/circled answer
Concomitant Drugs	As above with suspect drugs.	No	Aids causality assessment.	As above with suspect drugs.
Case Details, Narrative, Comments	Case narrative	No	Aids causality assessment and allows the reporter the opportunity to include any relevant information regardless of whether the form requests it. There should be a large space for this free text. This may replace the 'reaction field' where reactions and additional information are requested here. May include explanation of information to provide such as pregnancy details or test results, where applicable. NCAs can also indicate if reporters can attach additional pages if required.	Free text

Section	Field/Question	Mandatory for a valid report?	Value of the question	Suggested field format
Medical History	Past medical history	No	Aids causality assessment. Past history can help understand the patient characteristics better, e.g., if an ADR is received citing 'arrhythmia', but we see they have previously experienced a heart attack, then this will be important in the assessment of the case.	Free text
Additional Fields	Medication error	No	Aids causality assessment.	Tick box/circled answer and free text.



### Additional fields to consider including on a paper form

Section	Field/Question	Mandatory for a valid report?	Value of the question	Suggested field format
Patient	Is the patient pregnant?	No	Additional information helpful to gain understanding of exposure during pregnancy and potential impact on the foetus.	Tick box/circled answer
Suspect drug	Rechallenge	No	Aids causality assessment. This can affect the strength of evidence for a causal association.	Tick box/circled answer
Medical History	Past drugs	No	Additional information.	Free text
Additional Fields	Suspect drug source/where the drug was obtained	No	Additional information.	Free text
Additional Fields	Permissions to contact healthcare professional and contact details	No	Allows follow up to be requested indirectly for consumer reports with their healthcare professional.	Tick box/circled answer and free text.