The form of the form

Uppsala Monitoring Centre

Examples and good practice in designing an ADR reporting form

A national Adverse Drug Reaction (ADR) reporting form is used for collecting information about a suspected adverse event for analysis at a national pharmacovigilance centre. This document will help you design a user-friendly form and ease the process of submitting reports.

ADR forms are still the main way for sharing information between people who experience an adverse event and decision makers in the national healthcare system. Correct and timely information is necessary to make the risk-benefit analysis of medicines that can prevent future problems. This document will focus on ADR forms, both printed and online, for reporting Individual Case Safety Reports (ICSRs).

A well designed form will encourage and support the reporter in providing good quality ICSRs.

Helping the reporter to understand the ADR form and making the workflow as easy as possible is an important part of successful pharmacovigilance. Another important aspect of making ADR forms is to decide what information you need to collect; to know more about that, please read the UMC's document "ICSRs and VigiBase – the vital importance of quality" (available on the UMC homepage via this link).

Know your reporter

The first question to ask when designing an ADR form is '**who** will fill it in'? Will it be a healthcare professional or a patient? Will the form be filled in under stress before seeing the next patient or done carefully at home? The answer to this question will influence all other decisions you make about the design of the form. **Figure 1** shows the patient online reporting form in Australia where the patient is asked for their story, and not using medical terms.

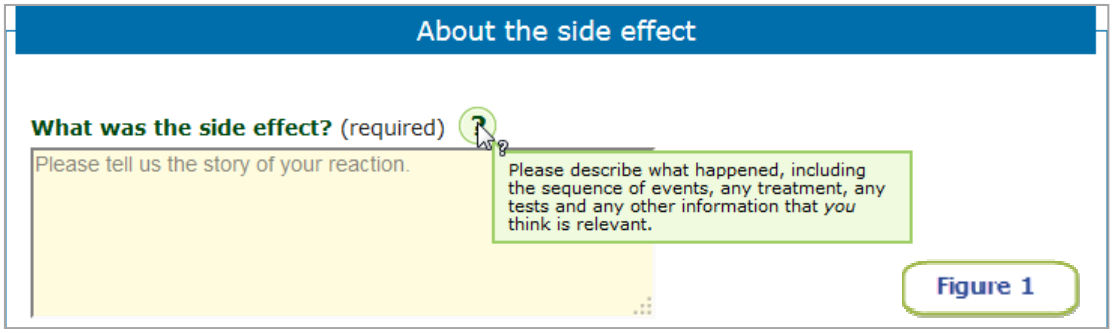


Figure 1

Use colours

Only using black text on white background will make your form disappear easily in general piles of paper. Using colour will make it stand out and be more attractive to the reporter. In some countries, the "Yellow card" is a well known name for the ADR reporting form, if that is also the case in your country, then you can use yellow as part of your design!

Online form – using colour online is free, so anything from coloured areas to photos is possible. The Croatian online patient reporting form in **Figure 2a** uses both.

Paper form – use coloured paper as on the Singapore paper form in **Figure 2b**, or tints of the same colour to create a multicoloured effect, as seen in the Netherlands paper form **Figure 2c**; using tints of the same colour can keep down the costs of printing compared to multi-coloured printing.

Figure 2a

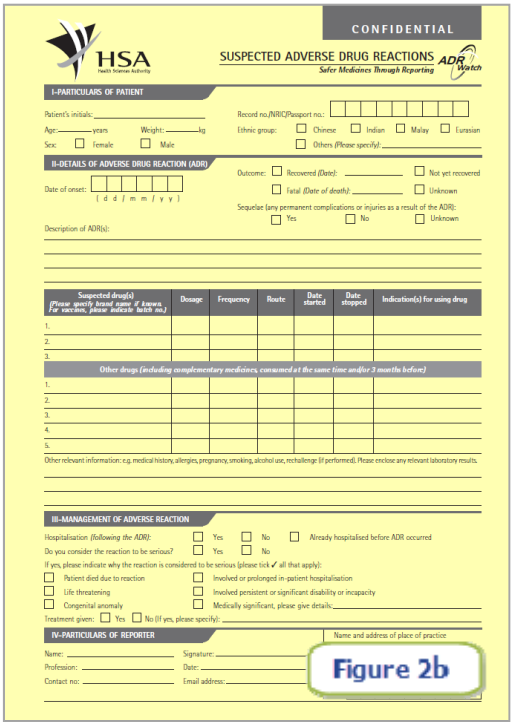


Figure 2b

Figure 2c

Include your logo

Ensure that the logo of your pharmacovigilance centre is clearly visible on the form – it should be obvious who the form comes from. Below are examples of logos from **Figure 2**.

Have a clear structure

Use colour, font size and headings to emphasize subsections in order to create a clear structure and make it easy to know what type of information is required in each section. The Singapore online form in **Figure 3a** uses dark blue headings and the paper form from Saudi Arabia in **Figure 3b** has blue and green headings.

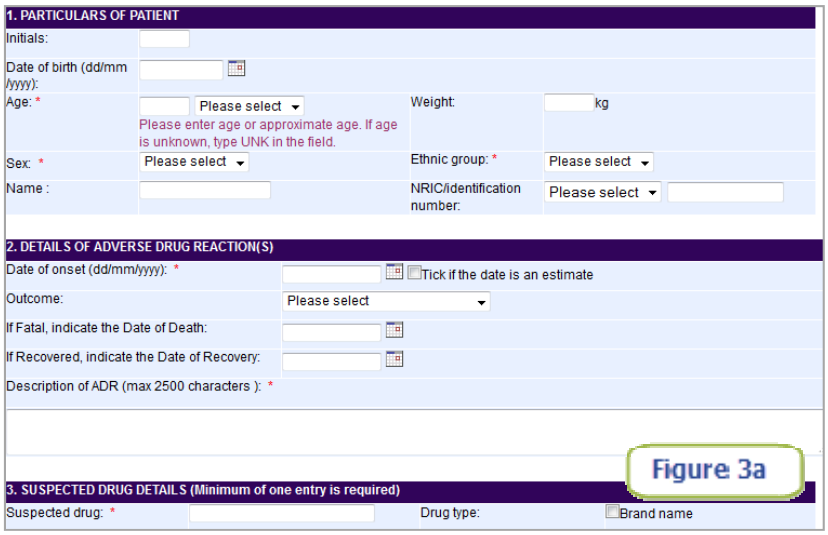


Figure 3a

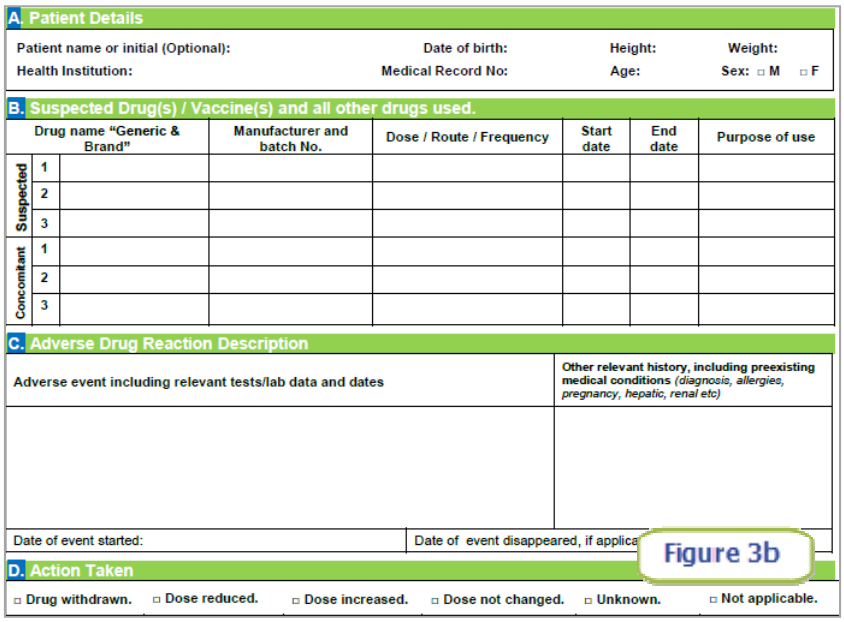
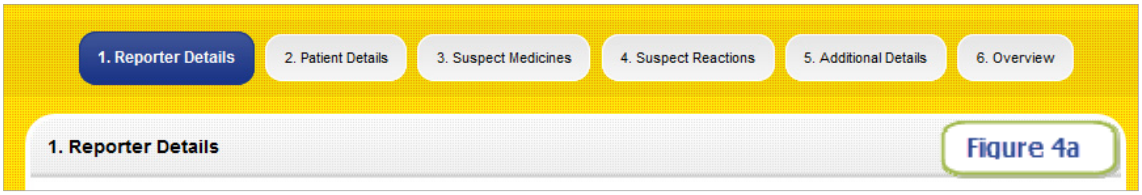


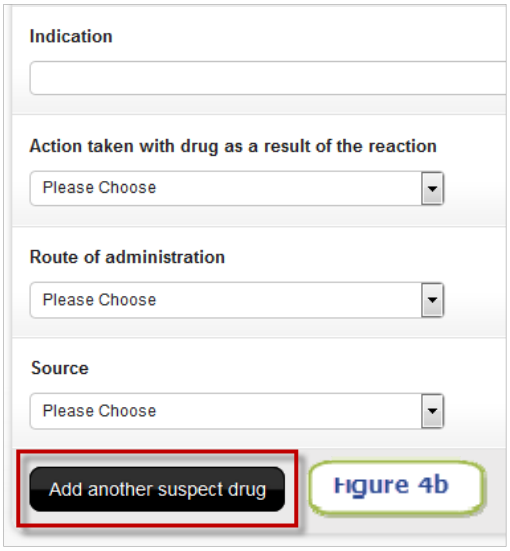
Figure 3b

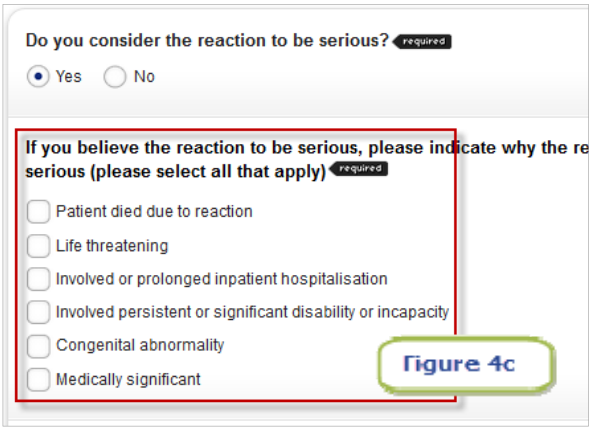
Make it short and clear

While keeping all essential fields, try to make your form as short as possible; your reporters will thank you.

Online form – use the possibilities without the limitations of paper size. Leave free space around the fields; this makes forms more inviting (see for instance **Figures 2a**, **4b** and **4c**). You can divide the form in several tabs, to avoid a very long single webpage, as seen in **Figure 4a**. Use the expand and collapse approach for repetitive information, for instance when there is more than one drug or ADR (**Figure 4b**), and to show more detailed questions when it is relevant. In **Figure 4c**, if the reporter answers "yes", an additional question appears. These approaches make the form look shorter, but all necessary fields can still be included (see **Figures 4a**, **4b** and **4c** from the UK online reporting form.) Another possible way is seen in the example from Saudi Arabia (**Figure 4d**) where the subsections are minimized to give an overview and allows the reporter to open sections one by one.







Paper form – keep the form, including help texts and other information, within one sheet of paper, maximum two pages long (using the front and back sides of the sheet). Use all space available on the sheet, having good layout in mind. See for instance **Figures 2b** and **2c**, as well as **Figures 5a** and **5b**. Consider field sizes and how well they correspond to the text

that should fit in them. If your paper form has big unused areas, you should check that you have not forgotten essential fields or have several very small fields, difficult for the reporter to write in. The one-page reporting form from the Philippines uses space wisely (**Figure 5a**) and the example from Saudi Arabia keeps the fields together on the first page and has guidelines, contact information and a thank you on the back (**Figure 5b**).

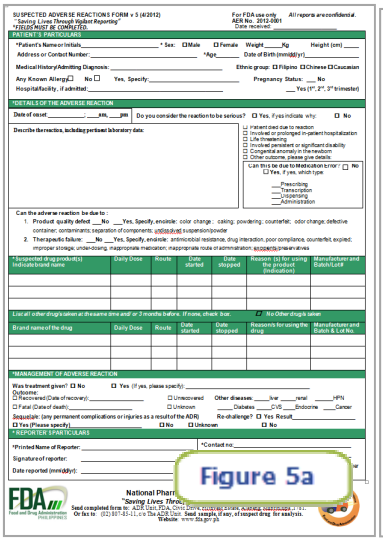


Figure 5a

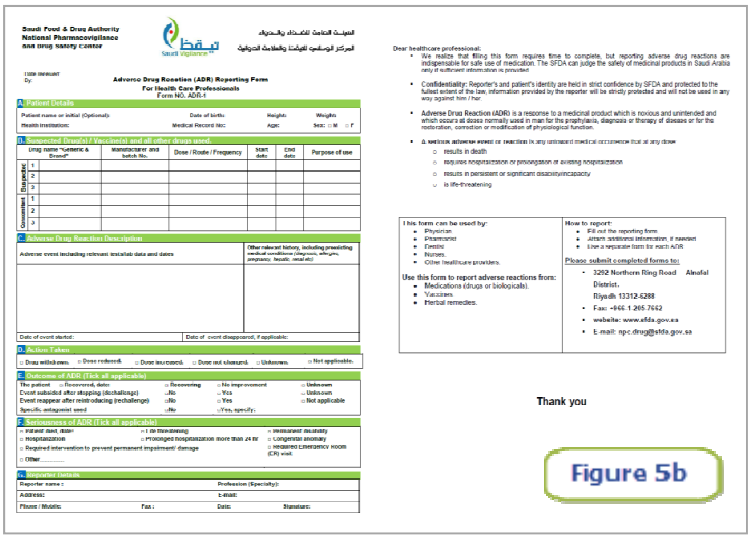


Figure 5b

Make it easy to understand

Using clear language is important on both paper and online forms. Make sure that field names are understandable and self-explanatory. Avoid complicated words, technical terms, abbreviations (unless you write them out) and unclear phrases. Clear language will save time for the reporter and reduce the risk of misunderstanding.

Some explanatory texts may be needed to help the reporter understand who can report, that data will be confidential, what drug and drug problems to report and how to fill in the form.

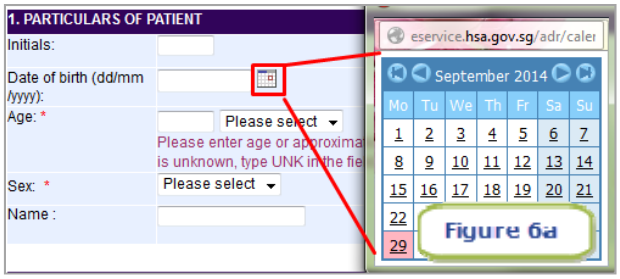
Online form – use the possibility to include many explaining texts, since there is an option to hide them and the reporter can choose to open them when needed. Hide texts behind question marks, as done on both the Australian form in **Figure 1** and on Croatian form in **Figure 7a**. Provide general guidance on top of a tab, as seen in **Figure 7b** with the ℹ sign on the UK form.

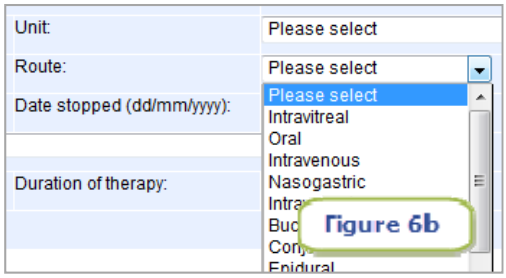
Paper form – use the reverse side for explanatory texts provided in an easily readable format. See the second page of the Saudi Arabian form in **Figure 5b**. If using one page only, make sure to include the most important statements at the top or bottom of the page.

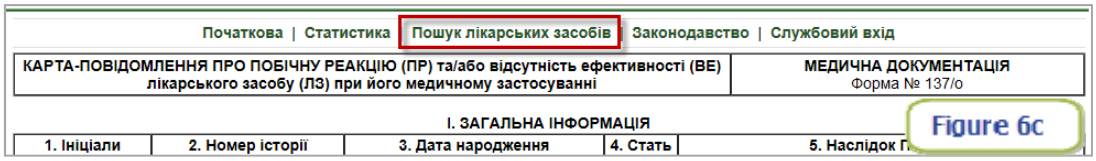
Use time-saving options

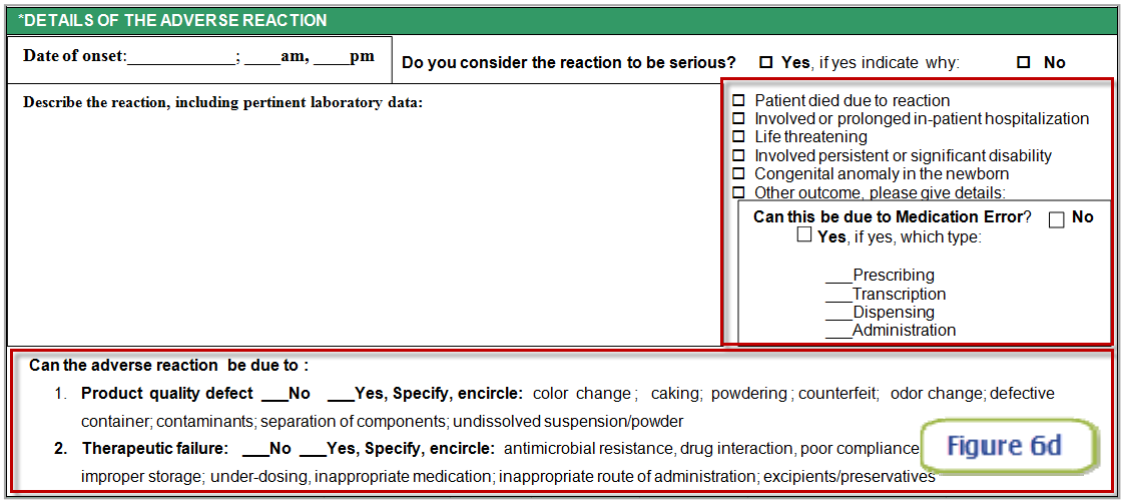
Time matters, and we all want to do things quickly. Invest time in designing the form in order to save time for reporters, but be careful not to make short-cuts or assumptions that will decrease the value of the information instead.

Online form – these forms offer a great variety of options that will both save time and improve the quality of entered information. Use tick boxes to offer a ready set of appropriate answering options (**Figure 4c**). Incorporate calendars into date fields to minimize date format mistakes (**Figure 6a**, example from Singapore). When there are many known alternatives answers, include drop-down menus, for fields such as route of administration or dose units (**Figure 6b**, also Singapore). Incorporate terminologies in the form, for example the national drug register, alternatively, or create a link from the form to where the reporter can browse the terminology. **Figure 6c** shows a form from Ukraine with a direct link to the national drug register. Use of these options will structure data and minimize misspellings etc., thereby lowering the risk of misinterpretation.









Paper form – here one can use tick boxes and the possibility to encircle the correct answer to allow a simple way of providing information without writing out answers. The Philippines paper form in **Figure 6d** has both tick boxes (marked area to the right) and encircle answering options (marked area at the bottom). Other examples of these options can be found in **Figures 2b**, **2c**, **5a**, **5b**.

Mark obligatory fields clearly

Some information is necessary for you to be able to interpret the data; these fields need to be clearly marked. Do not make all fields obligatory; then you risk that the reporter will invent information they do not have, to be able to complete the form.

Online form – use a different colour and/or text to clearly mark which fields are obligatory in contrast to other, important but not essential, fields. Make it obvious to the reporter that all fields don't have to be filled in to make a valid case. The Croatian online form has red asterisks by the mandatory fields (**Figure 7a**) and in the UK form the field are marked with required (**Figure 7b**); in both forms, the meaning is explained at the top of the page. You could make it impossible to submit an online report if obligatory information is missing.

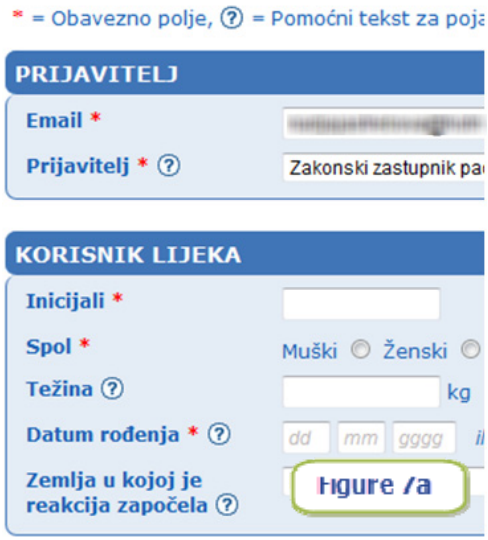


Figure 7a

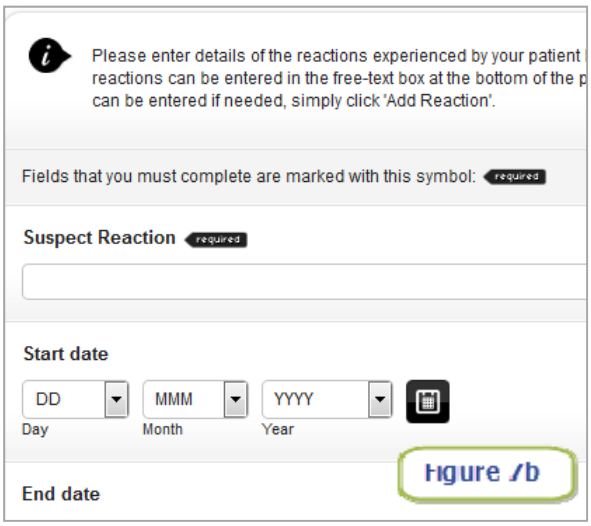


Figure 7b

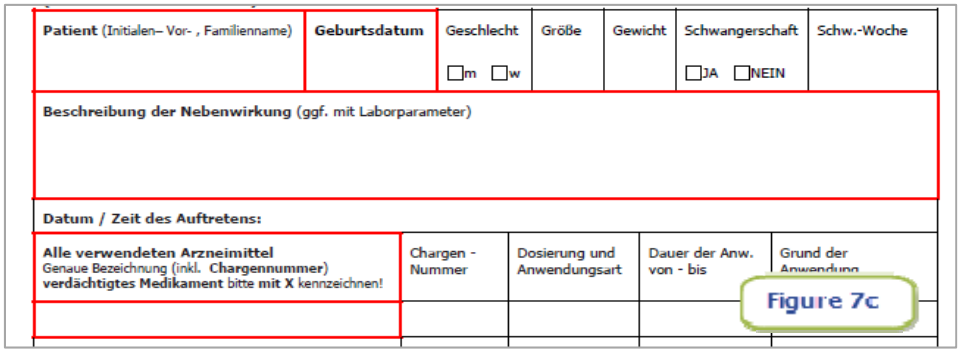


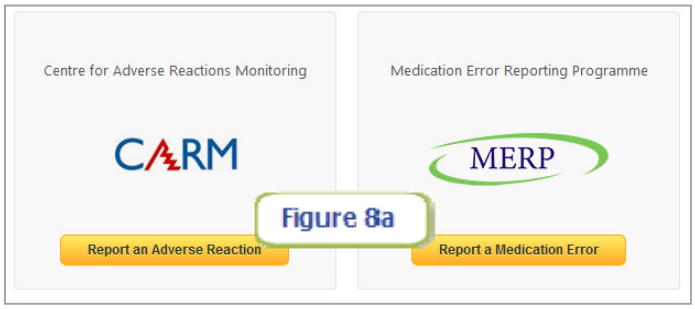
Figure 7c

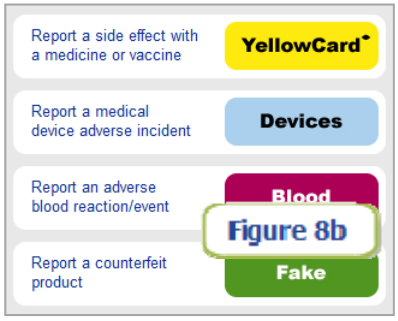
Paper form – use a different colour to highlight obligatory fields, or mark the field name with an asterisk (*); space limitations will make it harder to fit in anything bigger. The example with red borders in **Figure 7c** is from Austria.

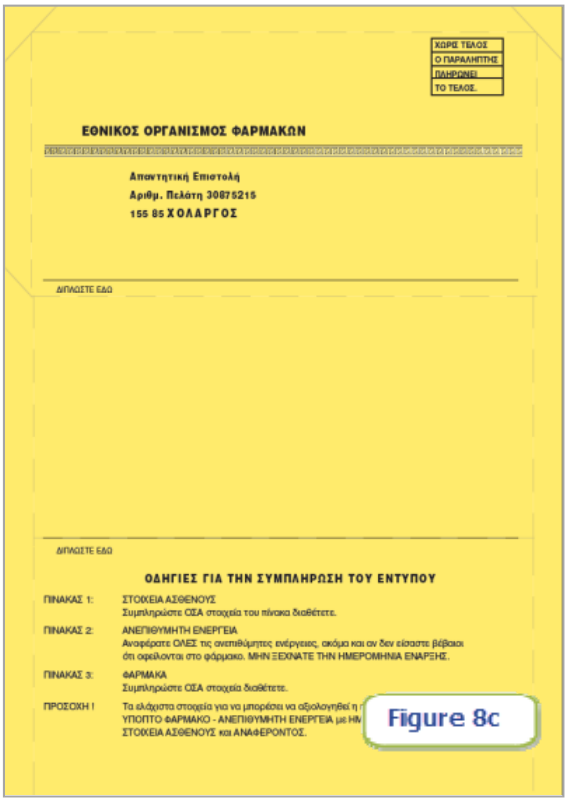
Make it easy to find and send

If the reporter cannot find your form, or does not know where to send it, you will never get the information you need. So make the form easily available and offer several ways to submit filled in forms.

Online form – make it easy to find the form on your homepage. Have a direct link from the main page to the online form or to a page where all reporting options are gathered. **Figure 8a** from New Zealand and **Figure 8b** from UK show how these links on the main page can look. Have a clear and visible submit button (complete/send in – use what is most understandable in your country!) at the end of report.



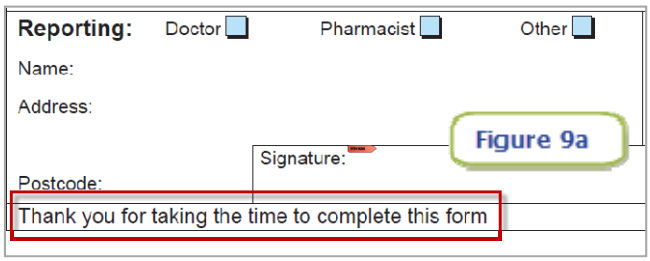


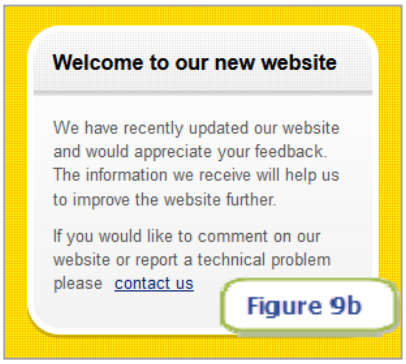


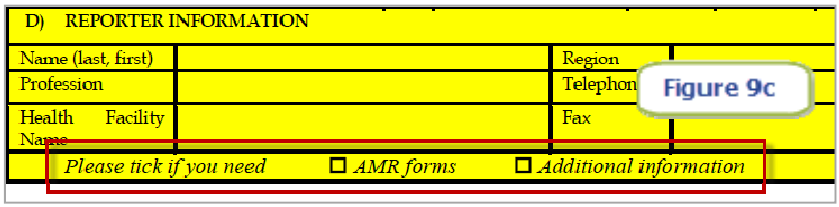
Paper form – make the form easily available both in paper and on your homepage for printing. Have the return address written on the second page together with prepaid postage, so that posting the form is free for the reporter. The form from Greece in **Figure 8c** shows this – with the additional value of instructions on how to fold the form into a letter. Offer several options for returning it and inform the reporter about an online reporting option if relevant; see an example from Singapore in **Figure 8d**.

Feedback

The reporter has made an effort to fill in your form, so a "thank you" note on the form is very important! You can also add that you have received information and that their contribution is valuable. Include, if possible, relevant information about the reported drug and/or ADR in your answer. Ask reporters for positive and negative feedback about the form in order to find out how to improve it. In an online ADR form one can include a few form-related optional questions at the end, so that feedback is provided directly after using the form. The thank you note in **Figure 9a** is from Australia, the invitation to comment on the new website in **Figure 9b** is from the UK Yellow Card online reporting, and the question if more forms or information is needed in **Figure 9c** is from the paper form in Namibia.







All examples shown in this document are from member countries in the WHO Programme for International Drug Monitoring.

Remember – an ADR form is never 100% perfect, there is always something that can be improved!

You can contact us at the UMC for questions and feedback – either getting feedback on your ADR form or giving feedback to us – at: vigibase@who-umc.org