

SCOPE Work Package 4 ADR Collection

**Feedback to
Patient ADR Reports**



SCOPE

Feedback to Patient ADR Reports

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1. Introduction

1.1 Purpose of the document

The purpose of this document is to provide National Competent Authorities (NCAs) with a proposed text for feedback to patients' Adverse Drug Reaction (ADR) reports.

1.2 Background

The Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action has been created to support operations of pharmacovigilance (PV) in the European Union (EU) following the requirements introduced by the 2010 European PV legislation^{1,2,3}, which came into force in June 2012. Information and expertise on how regulators in Member States (MSs) run their national PV systems was gained in order to develop and deliver guidance and training in key aspects of PV, with tools, templates and recommendations. The aim of the SCOPE Joint Action was to support consistent approach across the EU network for all PV operations, in order to benefit medicines safety monitoring and communications to safeguard public health.

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

WP4 ADR Collection was focused on national schemes for the spontaneous reporting of ADRs and was aimed to provide National Competent Authorities (NCAs) with a full understanding of and good practices within national systems for collecting ADRs. Information was gathered from European MS institutions to understand their national ADR system, PV IT system capabilities, as well as implementation of patient reporting, types of reporting forms developed, and electronic reporting developments, including those from clinical healthcare systems. This information was used to create best practice guidelines, performance indicators and a media toolkit for raising awareness of ADR reporting systems which will be supported through delivery of a training course for institutions.

¹ Directive 2010/84/EU of the European Parliament and of the Council

² Regulation (EU) No 1235/2010 of the European Parliament and of the Council

³ Commission Implementing Regulation (EU) No 520/2012

2. Feedback to patients – deliverable overview

Because of the growing number of reports of ADRs in general, as well as those from patients, the focus of this deliverable is on what information can be included in NCA feedback to patients to their reported ADR.

The results of the survey have shown that most MSs provide feedback to patients with regard to their reported ADR – notably, 24 MSs out of 28 that responded.

Providing feedback is considered beneficial for patients because, through it, the NCA informs and guides the patient. It also enables NCAs to build trust and raise awareness about the patients' role in the spontaneous reporting system. By providing feedback to patients, time otherwise used for answering patients' questions can be saved and patients can get clear information on what to expect from their NCA.

Responses to the survey show significant diversity of practices in different MSs. Different MSs have different systems for ADR processing, legal specificities in addition to the EU legal requirements, different number of employees in PV departments, different budgets, different IT systems, etc.

3. Acknowledgement, general and individual feedback

3.1 Acknowledgement feedback

Acknowledgement is a type of feedback in which an NCA confirms receipt of the reported ADR. Most MSs provide acknowledgements, which mostly consist of thanking the patients for their report and an explanation that the report will be further processed. This type of feedback is usually clear and concise with little or no additional information.

Depending on the NCA reporting system, sending additional information in the acknowledgement or after the initial acknowledgment in an individual feedback is an easy way of establishing valuable contact with the patient. In their feedback, NCAs could direct patients towards the Patient Information Leaflet (PIL) and/or Summary of Product Characteristics (SmPC) (in which case an explanatory note on the purpose of SmPCs should be included, e.g. that the document is aimed mainly at healthcare professionals), by providing a link to a medicinal products database or to product information, if possible.

Patients have become increasingly conscious about their health and wish to know more about the medicines they receive and could appreciate knowing about the importance of their role and contribution to medicine safety. The NCA can also provide information about the process of ADR data collection and related PV activities and how each individual report contributes to making drugs safer. Subscription to the NCA newsletter can be offered and means of reporting can be presented, so that patients become familiar with different ADR reporting tools and other NCA activities. For example, if available, an ADR app download link and social media buttons could be added to the feedback.

If technically possible, information on the database reference number of the patient-reported ADR can be included in feedback. This reference number makes easier all future communication about the reported ADR, and also gives patients insight into the NCA's ADR processing. All information provided should be written in layman's terms, so that it is easy to understand. The feedback should give the patient clear information on what to expect from their NCA. It should be made clear that advice on diagnosis and treatment of medical conditions cannot be expected from an NCA and patients should be directed to consult a doctor or other healthcare professional.

3.2 General feedback

General feedback should include more information than a short acknowledgement. It can be sent as an initial confirmation of the receipt of the patient reported ADR or it can be sent at a later stage on patient request along with a PV assessor's comment. It should be written in layman's terms and include as much relevant information as possible, such as:

- Database reference number
- Link to medicinal product database or to product information
- NCA activities
- Additional sources of information such as NCA newsletter
- Clear information on what to expect from NCA
- Advice to patients to consult a physician or other healthcare professional.

3.3 Individual feedback

Patients sometimes enquire about additional information relating to their ADR or other topics of their interest. If possible, NCAs can provide individual feedback to these requests. Information provided in individual feedback could be prepared by an ADR/PV assessor, but other NCA staff might also need to be included, such as PR staff, and it could include:

- Information about the ADR in the Patient Information Leaflet (PIL)
- Information from literature, information about previous reports in the database
- Information about NCA activities relating to a safety issue which is of interest to the patient
- Information on other topics within NCA competence requested by the patient.

4. Member State examples

Some MSs have systems which send automatically generated feedback, while others rely on individual drafting of each feedback. There are also examples where MSs use both automatically generated and individually drafted feedback. MSs use various channels for sending feedback, including email or post, as well as cases where patients have the option to log in online and receive feedback from the NCA.

- The Netherlands Pharmacovigilance Centre (Lareb), depending on the type of reaction, sends either a general feedback or individual feedback to patients. This feedback is generated in the Lareb system (Lareb2010). Individual feedback is written by the ADR assessor in a specific field in Lareb2010, after which this text is automatically integrated into the general acknowledgement letter (see [Annex 1](#)).
- State Institute for Drug Control (SUKL) in the Czech Republic receives patient reports mostly via a web form or by email. General feedback is sent after the report was received at the PV Department (see [Annex 2](#)).
- Norwegian Medicines Agency (Statens legemiddelverk, NOMA) receives patient reports via a web form within the same system that is used for other purposes, such as tax returns, and every adult in Norway is a user. It requires personal login credentials, and a copy of the report is saved in the reporter's personal mailbox within the secure system. NOMA provides general feedback to all reports received (see [Annex 3](#)).
- The Hungarian National Institute of Pharmacy and Nutrition (OGYÉI). ([Annex 4](#)) generally sends feedback via email or post as an acknowledgement of receipt. This acknowledgement is generated and sent automatically when the report is received and processed via the online reporting system. More detailed individual feedback is written by the assessor of the given case when a follow-up is deemed necessary. The relevant follow-up questions for clarification and explanatory notes are integrated into the acknowledgement letter. If the patient reports a general complaint not directly related to the ADR report itself, the response is composed and sent by another department, the Information and Utilisation Department.

5. Lareb research of feedback to patients

The Netherlands Pharmacovigilance Centre (Lareb) investigated the feedback for patients reporting ADRs.⁴ The objective of the research was to explore the satisfaction of patients towards individual and general feedback in response to their reported ADRs. Reporters received individual feedback or a general acknowledgement letter. Satisfaction towards the received feedback was studied using a web-based questionnaire. Data was analysed using the Pearson Chi-square test and linear regression analysis. A total of 471 patient-reporters were contacted with a total response rate of 52.5%. Respondents were satisfied with the feedback, average score 2 (good), but respondents of the individual feedback group considered the feedback more clear and useful compared with respondents of the acknowledgement letter group. Overall, patients reporting ADRs were satisfied with feedback received, they found it clear, useful and meeting their expectations, despite the differences between the two types of feedback.

⁴ Rolfes L, van Hunsel F, van Grootheest K, van Puijenbroek E: Feedback for patients reporting adverse drug reactions; satisfaction and expectations. *Expert.Opin.Drug Saf.* 2015;1-8

6. Feedback to patients – proposed text

Based on the arguments presented above, the feedback proposal has been created and any NCA can easily adapt it to suit their needs. The intention of the feedback is to make patients aware of the availability of relevant tools and sources of information, as well as to provide them with relevant information on drug safety and PV activities.

*Chevrons (<>) indicate where local information should be inserted.
Square brackets ([]) indicate optional items.*

Dear <name of reporter>,

Thank you for reporting to the <insert NCA>.

[The database reference number of your report is <insert reference number>].



Reporting adverse drug reactions to <insert NCA> enables us to gather new information about known adverse drug reactions and to identify previously unknown adverse drugs reactions. By reporting adverse drug reactions, you are helping to make medicines safer. Your personal data included in the report will be anonymized.

You can find more information about the medicine in the Patient Information Leaflet (PIL) and/or Summary of Product Characteristics (SmPC) here <insert link to medicinal products database or to patient information>.

Subscribe to our newsletter to receive the latest news in your email inbox <link>.

[If available, an ADR app download link can be added]

[If available, social media buttons can be added]

[For individual feedback, insert assessor's comment here]

[If you have any follow up questions, insert them here]

We might contact you in the future to ask for additional information about your report. We would appreciate it if you could also report any future possible adverse drug reactions to <insert NCA>.

Please note that <insert NCA> cannot provide advice on diagnosis and treatment of medical conditions. Consult your doctor or pharmacist for any additional information.

Best regards,

<insert NCA>

Annexes: Feedback examples

Annex 1. Netherlands Pharmacovigilance Centre Lareb



General feedback

Dear (name of reporter),

Thank you for reporting to the Netherlands Pharmacovigilance Centre Lareb. By reporting possible adverse drug reactions you contribute to the safer use of drugs and vaccines. Because all possible adverse drug reactions are reported to Lareb, we are able to identify unknown adverse drug reactions. It also enables us to identify new information about known adverse drug reactions.

Your report has been registered under the number 12345 and will be anonymised before being included in the Lareb database. Every adverse drug reaction report will be individually assessed by pharmacovigilance assessors. In addition, reports are discussed within a team of professionals, including doctors and pharmacists within Lareb.

At the moment we have no additional questions about your report. If we have any questions in the future, we will contact you.

If you have any questions or complaints, we advise you to consult your doctor or pharmacist. If you experience possible adverse drug reactions in the future, we would appreciate it if you would also report this to Lareb.

Best regards,

Within the Lareb system, individual information is automatically put into the general feedback.

Dear (name reporter),

Thank you for reporting to the Netherlands Pharmacovigilance Centre Lareb. By reporting possible adverse drug reactions you contribute to the safer use of drugs and vaccines. Because all possible adverse drug reactions are reported to Lareb, we are able to identify unknown adverse drugs reactions. It also enables us to identify new information about known adverse drug reactions.

Lareb recently published about aggressive behaviour during the use of antidepressant medication (SSRIs). Aggressive behaviour is described in the official information leaflet of fluoxetine. This reaction is mainly seen in users under 18 years. The type of adverse drug reactions and the extent to which they occur varies from person to person. Unfortunately this cannot be predicted. Recovery from the aggressive behaviour after withdrawal of fluoxetine may be indicative of a causal relation between the drug and the aggressive behaviour.

Your report has been registered under the number 12345 and will anonymized be included in the Lareb database. Every adverse drug reaction report will individually be assessed by a pharmacovigilance assessors. In addition, reports are discussed within a team of professionals, among others doctors and pharmacists, within Lareb.

At the moment we have no additional questions about your report. If we have any questions in the future, we will contact you.

If you have any questions or other complaints, we advise you to consult your doctor or pharmacist. If you experience possible adverse drug reactions in the future, we would appreciate it if you would also report this to Lareb.

Best regards,

Annex 2. State Institute for Drug Control (SUKL)



We are pleased with your interest in MP safety monitoring.
We thank you for reporting an ADR related to MP XX (drug name).

Your report was entered to the Czech ADR database with the number CZ-CZSUKL-XXXXXXXX. A report with this number and without your personal data (SUKL follows the rules given by the Office for the Personal Data Protection) will be forwarded to the European Union ADR database (EudraVigilance) and World Health Organization (WHO).

Every particular report, including yours, contributes to better risk benefit ratio assessment of the MP.

Best regards,

Annex 3. Norwegian Medicines Agency (Statens legemiddelverk, NOMA)



Reference number: AR

Thank you for helping us to monitor the safety of medicines. Consult your doctor if you have bothersome side effects. Your report can be found in 'My message box' under 'Archived'. NOMA cannot give you any personal feedback and the report cannot be traced back to you. You will receive a separate receipt with Medicines Agency's report ID number in 'My message box'. You will need this report ID number if you later contact NOMA regarding your report.

Send a copy of the receipt to your email ([link](#))

Annex 4. Hungarian National Institute of Pharmacy and Nutrition (OGYÉI)



Dear Reporter,

Your report on xxx adverse drug reaction experienced/observed with the use of yyyyy medicine was received on day/month/year by the zzzz (NCA). Your report is registered in the national database with the following unique case identifier number XY-12345. Please, note that our Institute also informs the concerned marketing authorisation holder about your report.

Provided that further information is deemed necessary on the case, the assessor processing your report will contact you. We kindly ask your cooperation with our colleagues gathering as much information as possible about the case for the purpose of determining the causal association between the adverse drug reaction and the suspected medicine. Proving or rejecting an association requires the most complete knowledge of the case and its circumstances.

Should you have further information on the reported case, please do not hesitate to contact us.

Thank you for your time and considerable efforts made in recognizing and reporting adverse drug reactions. With this practice you kindly contribute to medicines safety.