SAFETY MONITORING *of* MEDICINAL PRODUCTS

Reporting system for the general public

World Health Organization

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PREFACE

A handbook for consumer reporting of ADRs was discussed and requested at the thirty-first meeting of the National Pharmacovigilance Centres held in Uppsala, Sweden from 20–23 October 2008, and the development of this publication has been incorporated into the aims of the Seventh Framework Programme of the Research Directorate of the European Commission and its project Monitoring Medicines (http://www.monitoringmedicines.org/).

This document aims to provide practical guidelines on how to set up national systems for consumers to report adverse reactions to medicines. Throughout this document, the phrase "consumer reporting" is used to refer to reporting of adverse drug reactions (ADRs) by the general public.

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INTRODUCTION

In an increasing number of countries (e.g. Australia, Canada, Denmark, the Netherlands, Sweden, the United Kingdom, and the United States), consumers are being encouraged to report adverse reactions to medicines to a spontaneous reporting system, and organizations such as the World Health Organization (WHO) and the European Commission acknowledge the role of the consumer in spontaneous reporting (*1*). Consumers, patients and their organizations are becoming increasingly involved in pharmacovigilance, especially when it comes to risk communication (*2*, *3*).

Throughout this document, the phrase "consumer reporting" is used to refer to reporting of adverse drug reactions (ADRs) by the general public. Some countries use the term "patient reporting", but consumer reporting is a broader term, as not all consumers of medicines are patients. A patient may be defined as a person who receives medical attention, care or treatment from a physician or other health professional. The patient who buys an analgesic against a prescription from his or her physician, and the individual who buys painkillers at the pharmacy without consulting a health-care professional, are both consumers of a medicinal product.

This document aims to help countries set up a well-organized and effective consumer reporting system within their pharmacovigilance centre. Most national pharmacovigilance centres participate in the WHO Programme for International Drug Monitoring and it is recommended that ADR reports, including those from the public, be forwarded to the WHO International Individual Case Safety Reports (ICSR) database (*4*).

1. WHY CONSUMER REPORTING?

Unexpected and rare adverse reactions to medicines are mainly identified in the postmarketing phase. Since the early 1960s spontaneous reporting has been the main method of notifying adverse reactions. Traditionally, physicians have been the major source of spontaneous reports of adverse reactions. However, in some countries, pharmacists and nurses also play an important role in spontaneous reporting systems. The aim of spontaneous reporting systems is to detect new signals, and in order to do that, pharmacovigilance centres need many and good-quality reports. Underreporting of adverse reactions to medicines is a known problem (*5*). By receiving adverse reaction reports directly from consumers, and thereby tapping into an extra source of information on adverse reactions, the problem due to underreporting could perhaps be reduced. Also, there is evidence to show that new and novel adverse reactions can be detected through consumer reporting, and much sooner (*6*). In addition, consumers may also report unexpected benefits. However, consumer reports should never be considered as an alternative, but rather as a complement, to reports from health-care professionals.

Consumer reporting of adverse reactions could be useful for "over the counter" (OTC) medicines, herbal medicines, and for reporting problems with excipients and potential interactions. Consumers can provide detailed first-hand information about their experiences with medicines and how these medicines have affected their life. Their reports can help us understand how the medicines are actually used and can also highlight issues around lack of adherence (compliance). One drawback is that consumers seldom report a clear medical diagnosis, but the lack of medical knowledge can also be seen as an advantage, since consumers are likely to be less biased about what adverse reactions are already known and may therefore report reactions that seem unlikely from a medical point of view.

2. DEFINITIONS

Pharmacovigilance is "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem". The ultimate goal of pharmacovigilance is the rational and safe use of medicines, the assessment and communication of the risks and benefits of medicines on the market and the education of, and provision of information to, consumers about medicines. Self-medication with OTC and herbal medicines is a growing area and the possibility of experiencing an ADR or a safety concern following incorrect use should also be recognized for this group of products. It should be easy to report a suspected reaction, also for individuals who do not obtain their medicines on prescription.

A consumer report is a report of a suspected adverse reaction to a medicinal product as initiated by the consumer and without interpretation by a health-care professional. In some countries the actual reporting will be done directly by the consumers themselves or by a person close to the consumer (e.g. a relative), but in others reporting can be via a nurse or a pharmacist. In this case, a report is considered to be a consumer report if the health-care professional assisted the consumer only in the submission of the report and did not initiate the report, nor provide any additional information or interpretation to the report. If a health-care professional reports a personal experience of an adverse reaction to a medicine, this can be regarded either as a consumer report or as a health-care professional report depending on national interpretation.

3. HOW TO START A CONSUMER REPORTING SYSTEM

Before starting a consumer reporting system, it is strongly recommended to have in place a functional spontaneous reporting system for health-care professionals. There are several benefits of adding consumer reporting to an existing, functional system.

- Staff with knowledge in handling spontaneous reports are already available.
- A reporting form has already been developed and can be adapted for consumer reporting.
- Procedures for assessing reports have already been established.
- A database for storing reports is probably available.

If there is no pharmacovigilance centre and there is still a need for consumer reporting, the document *Safety monitoring of medicinal products: Guidelines for setting up and running a pharmacovigilance centre* (*4*) should first be consulted, as this document will provide more general information on how to set up a pharmacovigilance centre.

3.1 Basic steps in setting up a consumer reporting system

A plan should be prepared in accordance with the steps summarized below for the establishment of a consumer reporting system. This plan builds on an existing pharmacovigilance centre that already receives spontaneous reports from health-care professionals.

1. Contact the health authorities and consumer and patient organizations and explain the importance of the initiative and its objectives.
2. Design a reporting form (*see 4.1*) and start collecting data by distributing the form and making it available to consumers.
3. Develop material for educating consumers on the importance of reporting adverse reactions to medicines and explaining how their data will be used (*see 5.2*).
4. Ensure adequate training of pharmacovigilance staff in the assessment of consumer reports. Areas where specific training is needed include:
   - — data collection and verification
   - — interpreting and coding descriptions of adverse reactions
   - — coding of medicines
   - — case causality assessment
   - — signal detection
   - — risk management.
5. Establish a database or use an existing one (administrative system for the storage and retrieval of data; *see also 7.1*).

4. REPORTING OF ADVERSE REACTIONS TO MEDICINES

Spontaneous reporting, through a regional or a national system, is currently the major source of information on adverse reactions available for use in pharmacovigilance.

4.1 Reporting form

A case-report for the purposes of pharmacovigilance can be defined as: "A notification relating to a patient with an adverse medical event (symptom, sign or laboratory test abnormality) suspected to be induced by a medicine" (*4*).

If the same form is used for consumers and for health-care professionals, the text will have to be understandable by the layperson, otherwise using a separate form for consumers is encouraged. Mandatory fields usually include information related to the reporter, the consumer or patient (age, sex, initials), at least one adverse reaction and at least one suspected medicine, these being the minimum requirements for a valid report. While the reporting form should avoid being too extensive, it is valuable if it can collect information on the following elements:

- **The patient or consumer**
  Brief medical history (when relevant) of the person who experienced the adverse reaction. The level of detail may depend on national privacy and data protection legislations. In some countries it may be desirable to record ethnic origin, due to the possibility of different ethnic groups experiencing different responses to some medicines.
- **Adverse event**
  Description of the adverse event (nature, localization, severity, and characteristics), results of investigations and tests, start date, treatment and outcome.
- **Suspected medicine(s)**
  Name of the medicinal product (trade name, scientific name or common name, or active ingredient and manufacturer), dose, routes of administration, start and stop dates, indication for use, and for vaccines and other biologicals, a batch number may be important.
- **All other medicines used (including self-medication)**
  Names, doses, routes of administration, start and stop dates. Experience has shown that consumers are able to distinguish between the suspected medicine and medicines used concomitantly.
- **Risk factors**
  Examples of risk factors include impaired renal function, previous exposure to the suspected medicine, previous allergies, and social drug use.
- **Name, address and telephone number of reporter**
  For consumer reporting the contact details are to be considered confidential and to be used only for data verification, completion and case follow-up. The consumer is often also the reporter, but sometimes the reporter can be a different person, e.g. a relative.

In addition, the following items of information can be asked for on the consumer reporting form:

- **Place of purchase**
  Details on place of purchase are useful for any additional/follow-up information and also for detecting counterfeit medicines and their sources. This item of the reporting form could list different options such as a pharmacy, health store, abroad (another country), or Internet purchase. If appropriate, even the name of (for example) the pharmacy could be asked for.

- **How the consumer obtained the medicine**
  It can be useful to know if the medicine was obtained OTC or through a prescription. If prescribed, further useful data may be retrieved (see Medical confirmation of the event).

- **Severity of the adverse reaction**
  The severity of the adverse reaction can be categorized by asking, for example, to what extent the reporter's everyday life has been affected.

- **Seriousness**
  The consumer can be asked, for example, if the adverse reaction has led to consequences such as persistent or significant disability or incapacity, hospitalization, prolongation of existing hospitalization, a requirement for acute or intensive care, sick leave, birth defect, risk of death or death.

If appropriate and in order to enable detection of duplicate reports, the name of the prescriber can be requested. Alternatively, duplicate reports may be detected by asking if the consumer has informed anyone in the health care system about the adverse reaction. If the answer is yes, the profession of the prescriber (e.g. physician, dentist, nurse or midwife) should be requested. Duplicate reports can then be identified by matching the reports from the different categories of professionals within the database.

Reporting forms can have various contents and designs. Two different reporting forms have been translated into English and are provided in the annex. They should be seen as examples offering suggestions on what to include in a consumer reporting form.

4.2 Means of reporting

Reporting should be as easy and cheap as possible. Reports may be submitted using postage prepaid or business reply paper reporting forms, by telephone, fax or electronic mail or over the Internet. Distribution of paper forms to locations visited by consumers and patients is also a good option, e.g. the local pharmacies, health-care facilities or offices and/or in the magazines produced by patient organizations.

Many factors influence the choice of reporting means for a specific country. Receiving reports over the telephone or through local pharmacies might be the best solution for some countries, especially those where literacy rates are not high, while in other countries this option might be considered too resource-demanding compared to an electronic reporting form sent over the Internet.

4.3 What to report?

For spontaneous reports from consumers, it is recommended not to set any restrictions on the type of medicines and/or adverse reactions to be reported. Therefore reports on all suspected adverse reactions to medicines – known or not, serious or not – are welcome and useful. Reports on known and/or minor reactions can provide extra information on the use of a medicine, on adherence (compliance) to the prescribed treatment regimen, and reasons for non-adherence (non-compliance). Increased frequency of a given reaction can also be detected with the help of consumer reporting. Adverse reactions associated with all medicines, including traditional ones (e.g. herbal remedies or homeopathic medicines) should be considered.

Consumer reporting is also suitable for reporting of medication errors, for example when the wrong dose has been prescribed, dispensed or taken by the patient, and for reporting problems with medical devices, for example inhalators for medical substances. Lack of efficacy, which can be a sign of counterfeit medicines, is an important area where consumer reporting would be useful.

In addition to registered medicinal products, the pharmacovigilance centre may also wish to collect reports on dietary supplements and cosmetics, especially since these products may contain obsolete or toxic ingredients, or sometimes pharmaceutical substances that have been illicitly included.

5. SPECIAL ISSUES IN REPORTING

5.1 Central or decentralized reporting?

As a rule, spontaneous reporting systems aim at country-wide reporting and the use of one central pharmacovigilance database to obtain a national overview. For reporting by health-care professionals, the collection of data may nevertheless be more successful, in terms of number and quality of reports, if reporting is organized regionally, since the regional centres are geographically closer to the health-care professionals. This is especially true when countries are large and have regional differences in culture and language.

The focal point for consumer reporting should be adapted to the needs of the country concerned. Having an identical structure and system for reporting by health-care professionals and by consumers is not necessary. Central reporting might be advisable if a country is homogeneous regarding language and culture; stimulation of reporting can then be coordinated centrally. In a centralized setting it is also possible for assessors to develop comprehensive skills in assessing consumer reports since they will each have the opportunity to assess more reports than would be the case for assessors in regional centres. In some countries the decision has been made to keep the consumer reporting on a central level, even though the regular pharmacovigilance work is allocated to regional centres.

If there are wide differences in culture and language, it might be advisable to have a decentralized consumer reporting system, since each region knows best how to promote reporting in its own area and is able to communicate with the consumers in their own language.

5.2 Stimulation of reporting

The reporting of adverse reactions needs continuous stimulation. It is important to promote knowledge and understanding of pharmacovigilance among consumers, thereby motivating them to share their experiences. The following list summarizes ways in which reporting may be stimulated:

- easy access to prepaid reporting forms and other means of reporting;
- a clear and user-friendly reporting form with easy instructions;
- acknowledgement of the receipt of adverse reaction reports by personal letter or telephone call, or by an automated electronic receipt;
- provision of feedback to reporters through statistics on a website or special newsletters aimed at the public;
- participation of the centre's staff in meetings of specific patient organizations;
- education about pharmacovigilance and the importance of reporting, for example among schoolchildren, in faith-based or other social organizations, and communities as a way of stimulating awareness and reporting;
- increasing the general knowledge about medicines and their potential adverse effects, and the possibilities of reporting adverse effects;
- provision of information through radio or television programmes or by local pharmacies;

- investigating what the consumer in a specific country expects and needs from the reporting system;
- if funds are available, producing an information leaflet or posters; the Internet could be an inexpensive solution for some countries, but buying advertisements on the Internet can be costly (e.g. for diverting Internet searches via search engines to a specific pharmacovigilance website).

5.3 Medical confirmation of reports

It is also useful to consider the possibility of communicating with the consumer's physician to request additional information, such as laboratory data and data verification. If a consumer report during follow-up is "medically confirmed", the report should be updated and handled according to the regulations governing medically confirmed reports. For example, the phrase "medically confirmed" is used in the European legislation and refers to a case-report where the suspected adverse reaction is confirmed by a health-care professional.

5.4 Consumer reports received by the pharmaceutical industry

Regulations may differ between countries, but usually the system for sending consumer reports directly to the industry is different from the national pharmacovigilance centre's consumer reporting system. The pharmaceutical industry has to follow the guidelines which regulate it (e.g. Volume 9A within the EU (*7*)).

6. PRACTICALITIES IN THE ORGANIZATION OF CONSUMER REPORTING

6.1 Staff

In addition to the expertise desirable in the routine work of a pharmacovigilance centre, staff dealing with consumer reporting may need extra training and specific experience in handling and interpreting consumer reports (*see also 6.3*). In the initial phase, running a consumer reporting system, including analysis of reports, may be more time consuming than running an already existing system handling reports from health-care professionals.

6.2 Equipment needs

No equipment additional to that used in handling reports from health-care professionals is needed, except perhaps a medical dictionary for the coding of adverse reaction terms into WHO Adverse Reactions Terminology (WHO-ART) and/or Medical Dictionary for Regulatory Activities (MedDRA) terms. If a consumer reporting form comprises fields other than those that appear in the form for health-care professionals, the database might have to be adjusted with additional fields (e.g. two separate fields for ADRs; those originally described by the consumer and those interpreted by the report assessor).

6.3 Special training needs

Consumers tend to describe symptoms using a narrative form instead of reporting diagnoses and, therefore, training the relevant staff in interpreting and coding the adverse reactions reported by consumers is vital. In addition to coding the symptoms described by the consumer into terms used in the hierarchical terminology of choice without interpretation, it may also be useful for the assessor to try to recognize a cluster of symptoms as indicative of a certain disease. These assessors' and senders' diagnoses should be added to the database structure (already available in the E2b-format used by ICH countries). It is however important to remember that the "assessor's diagnosis" is merely a diagnosis suggested by the report assessor who has not met the patient, in contrast to the diagnosis made by a reporting physician.

Communicating with consumers is clearly different from communicating with health-care professionals. The consumers have different backgrounds and different levels of prior knowledge of medicines and their benefits and risks. If there is direct communication with the consumer (e.g. through individual feedback, via a website or through publications) it is important to gain knowledge on how to communicate with consumers most effectively. This might mean using different phraseology and communication on an individualized level.

6.4 Input from consumers

Collaboration with consumer and patient organizations can be vital in order to create a rewarding consumer reporting system for all parties. What role the consumers should play can vary, but there are several levels on which their input can be of interest. Showing the

consumers, patients and their organizations that their input is valuable can motivate the consumers to report adverse events.

On a practical level, the consumers and their organizations may be helpful in making the reporting form more user-friendly by suggesting improvements to the language and assisting in developing accompanying guidance texts. They can also suggest alternative ways of reaching consumers and patients. It is important to aim for a reporting system that enables individuals with disabilities (primarily visual impairment) to have access to the system.

6.5 Information service

It is important to provide general information on medicines to consumers. Access to up-to-date information on medicines and their side-effects is necessary to help consumers learn more about their medicines. This information can be presented on a website, often with a special landing page for consumers, or provided by a telephone service. Alternatively information can be given in leaflets or on posters.

6.6 Communication

Communicating with consumers clearly differs from communicating with medical professionals, for example, in the level and detail of information. To create successful communication with the public it is necessary to think about what sort of information to communicate, on which level this has to be done, and through which channels. Certain patient groups can be reached through patient organizations acting as intermediaries.

Personalized information is given to the consumers in some countries. Regarding individual treatment advice, however, many countries refer back to the patient's treating physician or to their pharmacist.

An automated acknowledgment of receipt for electronically submitted reports gives the consumer confirmation that the report has been received. General feedback can be given to the public through case-report summaries and statistics on a website, or in a specific newsletter aimed at the public.

7. ASSESSMENT OF CASE-REPORTS

The assessment of any case-report on an adverse reaction needs expertise in clinical medicine and pharmacology. In addition, assessment of consumer reports requires experience in interpretation of the information on severity and seriousness that consumers often include in their reports. The following elements of the case-reports should be assessed:

Quality of documentation

The basic elements of a case-report are listed in *4.1*. In addition to evaluating the quality and completeness of the data, as done on reports from health-care professionals, it is necessary to define how to grade the quality of consumer reports. The quality of diagnosis and of follow-up information can be included as quality criteria, but the initial consumer reports may contain additional and different information from that obtained in regular reporting, thereby giving them a distinctive value.

Coding

Names of medicines should be registered in a systematic way, for example by using the WHO Drug Dictionary (which is based on the International Non-proprietary Names (INN) nomenclature and the Anatomical Therapeutic Chemical (ATC) classification, and includes trade names). For the coding of the adverse events WHO-ART or another internationally recognized terminology (e.g. MedDRA) should be used.

Relevance

The following questions may be asked to support the use of consumer reports in the detection of new reactions, in the regulation of medicines, and with a view to improving the scientific or educational value of consumer reports:

- ***New medicine?*** Products that have been on the market for fewer than 5 years are usually considered new medicines.
- ***Unknown reaction?*** (i.e. a reaction which is not included in the approved summary of product characteristics. It is important to note whether the reaction is described in the relevant literature, e.g. national drug formulary, *Martindale*, or *Meyler's Side Effects of Drugs*.
- ***Serious reaction?*** (*see glossary*) Asking this question would be useful in detecting serious reactions, especially with OTC and herbal medicines.

Identification of duplicate reports

Detection of duplicate reports is important when introducing reporting from new sources and storing the data in one database. This is especially true when introducing consumer reporting since there is a risk that both the consumer or patient and the health-care professional will report the same adverse reaction. Certain characteristics (including sex, age or date of birth, and dates of exposure to the medicine) may be used to identify duplicate reports. It is important to be able to identify reports of the exact same reaction also when consumer reports are stored separately from reports made by health-care professionals. This

is particularly important in assessing a potential signal based on reports from different sources and/or databases (*see 4.1*).

Causality assessment

As with reports from health professionals, the case-reports from consumers mainly describe suspected adverse reactions to medicines. Various approaches have been developed for the structured determination of the likelihood of a causal relationship between exposure to a medicine and adverse events, for example, the methods developed by the WHO Programme for International Drug Monitoring (see glossary), the European Commission, and by the French national pharmacovigilance programme. These methods, which are also applicable to consumer reports, are largely based on five considerations:

- the association in time (or place) between administration of the medicine and the event;
- current knowledge of nature and frequency of adverse reactions
- medical or pharmacological plausibility (signs and symptoms, laboratory tests, pathological findings and mechanism);
- course of the event after cessation of the drug; and
- likelihood or exclusion of other causes.

The WHO causality categories have the advantages of being internationally agreed and easy to use.

Some adverse reactions have been defined by an international working group under CIOMS (*8*). For some of these reactions (e.g. hepatotoxicity), special causality algorithms have also been developed (*9, 10*).

7.1 Data-processing

The computer system already in place for filing reports from health-care professionals can also easily be used for consumer reports; the same hierarchical files of medicinal products and adverse reactions terminologies can be used. It may however be necessary to include some additional fields in the database structure allowing the more detailed information from the consumer reporting form to be entered (*see 6.3*).

Consumer reports can be stored in a separate database, but if all case-reports are stored in the same database irrespective of origin, it should be possible to identify the different types of reports (e.g. from health-care professionals, consumers, literature and study reports). Signal detection and studies of added value can then be performed , for example, with or without the case-reports from consumers or health-care professionals, adding further options for differentiated analysis. As far as possible, internationally recognized terminologies and classifications of medicines (ATC or INN) and of adverse reactions (e.g. WHO-ART or MedDRA) should be used to facilitate international comparisons of results and international transfer of data.

8. USE OF THE DATA

Consumer reports can be used in pharmacovigilance in a variety of ways. The following subsections describe examples of the added value of consumer reports.

8.1 Hypothesis generation and strengthening

A major aim of pharmacovigilance is the hypothesis generation and early detection of signals (see glossary) with regard to possible adverse reactions. Early signals may be too uncertain, however, to justify firm conclusions and regulatory action, and may need further study. A signal may be strengthened by combining the experiences reported in various countries. Therefore international collaboration is important. Consumer reporting can, besides adding to knowledge about prescription medicines, add to the knowledge on OTC and herbal medicines as well as on potential interactions. Considering that information may not be available on possible consequences of combining different medicines, particularly for medicines that are new on the market, it is important to receive information on possible interactions when using medicines for self-medication.

8.2 Medicine regulation

After approval of a medicinal product, all available domestic and international safety information is continuously monitored by the regulatory authorities and the pharmaceutical company concerned. For the approval of a given medicine in a given country, it may be valuable to have information on the experiences with the medicine in countries where it is already in use (e.g. through collaboration with the Uppsala Monitoring Centre). Often, problems can be solved by adaptation of the approved product information (e.g. by inclusion of new adverse effects, warnings, or changes in indication). Sometimes, however, stronger restrictive actions are needed, with withdrawal of the marketing authorization being the most extreme.

8.3 Information

Consumers are a large and heterogeneous group, and informing a target population might entail informing the whole population of a country. In order to disseminate information to such a broad group, one has to look for various ways to reach all its members at an acceptable cost. For the dissemination of information of immediate importance or interest to consumers, a website presenting summaries of case-reports and statistics can be an option. An electronic newsletter can keep consumers up to date with recent pharmacovigilance developments. If the information needs to be distributed in printed form, the same distribution channels as for the paper reporting form can be used. Information can also be distributed through radio and television channels and local pharmacies.

8.4 Education and feedback

When providing education and feedback about adverse reactions to medicines, one has to try to narrow down the target population, or focus on certain groups. Education of consumers and patients through their organizations can be efficient and effective. By increasing the knowledge and awareness of adverse reactions, reporting can be stimulated.

9. RELATIONS WITH OTHER PARTIES

9.1 Consumer or patient organizations

Support from national associations of consumers and patients may add to the general acceptance of pharmacovigilance. These organizations can also be valuable in distributing reporting forms, spreading information about adverse reactions to medicines and introducing a consumer-centred way of working in a pharmacovigilance centre. However, it is important to stress that all reports of adverse reactions should be forwarded to the national pharmacovigilance centre.

9.2 Medicine regulatory authorities

The national regulatory authority for medicines needs to be informed about suspected adverse reactions in the country concerned without delay, especially when these reactions are unusual (e.g. they are not included in the approved Summary of product characteristics) or serious. In addition, a pharmacovigilance centre that is not part of the regulatory authority needs to inform the regulatory authority about any cluster of case-reports that is of possible interest, or when an adverse reaction is reported with high or increasing frequency.

9.3 Pharmaceutical companies

When the national centre accepts consumer reporting, it is important to check existing regulations for information exchange with pharmaceutical companies, and if there is no legislation, the best way to exchange consumer report information with the pharmaceutical companies should be discussed.

9.4 Professional medical and pharmaceutical organizations

If consumer reporting is introduced in a country where a spontaneous reporting system for health-care professionals is already in place, it is important to inform professional medical and pharmaceutical organizations that consumer reporting does not, by any means, replace reporting by health-care professionals. Consumer reporting should always be seen as a complement to reporting from other sources.

9.5 World Health Organization

A pharmacovigilance centre that is about to set up a consumer reporting system should inform WHO, Geneva and the WHO Collaborating Centre for International Drug Monitoring in Uppsala, Sweden. Consumer reports should be forwarded to the Uppsala Monitoring Centre database in the same format as agreed for reports from health-care professionals.

9.6 National pharmacovigilance centres

In addition it may be helpful to make contact with other countries where a consumer reporting system is in place. If they already have more experience with consumer reporting, such centres may be helpful with staff training.

9.7 Media

Good relations with leading journalists may be helpful for general public relations whenever an acute problem with a medicine arises. Special attention may need to be paid to explaining to journalists the limitations of pharmacovigilance data (*11*).

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GLOSSARY

The definitions given below apply to the terms used in these guidelines. They may have different meanings in other contexts.

Adverse (drug) reaction (ADR)
A response which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.

An adverse drug reaction, contrary to an adverse event, is characterized by the suspicion of a causal relationship between the drug and the occurrence, i.e. judged as being at least possibly related to treatment

Adverse (drug) reaction (ADR) case-report
A notification relating to a patient with an adverse medical event (or laboratory test abnormality) suspected to be induced by a medicine.

Adverse event
Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment.

Synonym: adverse experience

Association
Events associated in time but not necessarily linked as cause and effect.

Benefit–risk analysis
Examination of the favourable (beneficial) and unfavourable results of undertaking a specific course of action. (While this phrase is still commonly used, the more logical pairings of benefit–harm and effectiveness–risk are slowly replacing it.)

Causality assessment
The evaluation of the likelihood that a medicine was the causative agent of an observed adverse reaction. Causality assessment is usually made according to established algorithms.

Compliance
Faithful adherence by the patient to the prescriber's instructions.

Effectiveness/risk
The balance between the rate of effectiveness of a medicine versus the risk of harm is a quantitative assessment of the merit of a medicine used in routine clinical practice. Comparative information between therapies is most useful. This is more useful than the efficacy and hazard predictions from premarketing information, which is limited and based on selected subjects.

Excipients
All materials included to make a pharmaceutical formulation (e.g. a tablet) except the active drug substance(s).

Formulary
A list of medicinal drugs with their uses, methods of administration, available dose forms, side-effects, etc, sometimes including their formulas and methods of preparation.

Generic (multisource product)
The term "generic product" has somewhat different meanings in different jurisdictions. Generic products may be marketed either under the non-proprietary approved name or under a new brand (proprietary) name. They are usually intended to be interchangeable with the innovator product, which is usually manufactured without a licence from the innovator company and marketed after the expiry of patent or other exclusivity rights.

Herbal medicine
Includes herbs, herbal materials, herbal preparations and finished herbal products.

National pharmacovigilance centres
Organizations recognized by governments to represent their country in the WHO Programme (usually the drug regulatory agency). A single, governmentally recognized centre (or integrated system) within a country with the clinical and scientific expertise to collect, collate, analyse and give advice on all information related to drug safety.

Over the counter (OTC)
Medicines which are available for purchase without prescription.

Pharmacovigilance
The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.

Postmarketing
The stage when a drug is generally available on the market.

Regulatory authority
The legal authority in any country with the responsibility of regulating all matters relating to medicines.

Serious adverse event or reaction
A serious adverse event or reaction is any untoward medical occurrence that at any dose:

- results in death;
- requires inpatient hospitalization or prolongation of existing hospitalization;
- results in persistent or significant disability or incapacity;
- is life-threatening;
- results in a congenital anomaly or birth defect.

To ensure that there is no confusion or misunderstanding of the difference between the terms "serious" and "severe", the following clarification is provided:

The term "severe" is not synonymous with serious. In the English language, "severe" is used to describe the intensity (severity) of a specific event (as in mild, moderate or severe); the event itself, however, may be of relatively minor medical significance (such as severe headache). Seriousness (not severity), which is based on patient/event outcome or action criteria, serves as guide for defining regulatory reporting obligations.

Signal
Reported information on a possible causal relationship between an adverse event and a drug, the relationship being previously unknown or incompletely documented. Usually more than one report is required to generate a signal, depending upon the seriousness of the event and the quality of the information. The publication of a signal usually implies the need for some kind of review or action.

Spontaneous reporting
System whereby case-reports of adverse drug events are voluntarily submitted by health professionals and pharmaceutical manufacturers to the national regulatory authority.

Unexpected adverse reaction
An adverse reaction, the nature or severity of which is not consistent with domestic labelling or market authorization, or is not expected from the characteristics of the drug.

WHO Programme for International Drug Monitoring
The WHO Programme that provides a forum for WHO Member States to collaborate in the monitoring of drug safety.

ANNEX 1. EXAMPLES OF CONSUMER REPORTING FORMS

In the examples below the questions in the consumer reporting forms have been translated into English and extracted into a summary tabulation.

A. Netherlands

A Adverse Reaction

- Suspected adverse drug reaction?
- Startdate of the reaction?
- How long were you taking the drug before the reaction started?
- Outcome?
    - Recovered
    - Recovering
    - Not recovered
    - Recovered with sequel
    - Death
    - Unknown
- Were there any other adverse drug reactions?
- Is/are the adverse reaction(s) treated, and if so with what?
- Has the reaction occurred previously while using the suspect drug?
- Are there any possible other circumstances or causes that could have caused the reaction or have aggravated it?
- Has the reaction led to any of the following situations?
    - Death
    - Lifethreatening
    - Hospitalisation
    - Permanent disabilities
    - Congenital abnormalities
    - Other serious reactions

B Drug

Suspect drug

- Suspect drug?
- Specify drug (scroll down for manufactures, dosages etc.)
- RVG code or EU code?
- Possible interaction?
- Startdate?
- Dosage?
- Indication?
- Has the use been adapted after the adverse reaction occurred?
    - Drug withdrawn
    - Dosage decreased
    - Dosage increased
    - No change
    - Unknown
    - Not applicable
- In case of stopping:
- Stopdate of the drug?
- Are you using any other drug that you find suspect?

Concomitant Medication

- Are you using any other – non suspect –drugs?

C Your personal information

- Sex?
- First Name/letter?
- Family name?
- Date of birth?
- Weight?
- Height?
- Email address?
- Address?
- Postal code?
- City?
- Telephone number?

D Information about the prescriber

- By whom was this drug prescribed?
    - general practitioner
    - medical specialist
    - no one (over the counter medicine)
    - not applicable (for example vaccination)
- Name of the prescriber?
- Address?
- City?

E Information about the provider

- Where did you collect the drug?
    - pharmacy
    - drugstore
    - not applicable (for example vaccination)
- Name of the provider?
- Address?
- City?

F Processing of the data

- Would you like to receive written feedback with respect to content about your report?
- Room for other commentaries
- Would you like to receive a conformation-email about this report with an overview?
- Do you agree with the privacy statement?

B. Sweden

The fields marked with an asterisk (*) are mandatory (sex, year of birth, at least one adverse reaction (either symptom or description in their own words) and at least one suspect drug).

About the person filling in the report

1. Name
2. Can the Medical Products Agency contact you? O Yes O No
3. Telephone incl. area code
4. E-mail address

About the person who experienced the adverse reaction

5. Who experienced the adverse reaction?
   - O Me
   - O My child
   - O Someone else: _____

6. Sex * O Male O Female
7. Date of birth (YYYY*- MM-DD)
8. Weight in kg
9. Length in cm

Adverse reaction

10. Describe adverse reaction symptoms* (one symptom per row)
11. The adverse reaction started (YYYY-MM-DD) (per symptom)
12. Describe the adverse reaction in your own words*
13. How long was the medicine used before the adverse reaction occurred?
14. Has the adverse reaction been treated?
    - ○ Yes, treated with: _____
    - ○ No
    - ○ I do not know
15. Has the adverse reaction disappeared?
    - ○ Yes, completely
    - ○ Yes, recovered, but with remaining symptoms
    - ○ No, but the reaction has decreased
    - ○ No, no difference
    - ○ I do not know
16. The adverse reaction has impacted on the everyday life as follows
    - ○ Little or not at all
    - ○ Has affected everyday life
    - ○ Has made everyday life impossible
    - ○ I do not know
17. Has the adverse reaction led to any of the following situations
    - ☐ Hospitalization
    - ☐ Prolonged hospitalization
    - ☐ Intensive care
    - ☐ Sick leave
    - ☐ Life-threatening reaction
    - ☐ Disability
    - ☐ Birth defect
    - ☐ Death
    - ☐ None of the above
18. Are there other diseases than the one that the medicine was used for?
19. Any other possible causes of the reaction?

Suspected medicine

20. Name of medicinal product*
21. Pharmaceutical form and strength
22. Reason for treatment
23. Dosage
24. Treatment start date (YYYY-MM-DD)
25. Treatment end date (YYYY-MM-DD)
26. Was the medicinal treatment changed when the adverse reaction occurred?
    - O Yes, stopped using the medicine
    - O Yes, decreased the dose of the medicine
    - O Yes, increased the dose of the medicine
    - O No
    - O I do not know
27. What happened when the treatment was changed?
    - O The reaction disappeared
    - O The reaction was reduced
    - O No change in the reaction
    - O I do not know
28. If the medicine has been used again, did the reaction reappear?
    - O Yes
    - O No
    - O I do not know
    - O Has not been used again
29. Where was the medicine obtained?
    - ☐ Pharmacy (without prescription)
    - ☐ Pharmacy (prescription by a doctor)
    - ☐ Pharmacy (prescription by a dentist)
    - ☐ Pharmacy (prescription by a nurse)
    - ☐ Pharmacy (prescription by a midwife)
    - ☐ Pharmacy (prescription by a dental hygienist)
    - ☐ Health food shop
    - ☐ Other shop
    - ☐ Internet
    - ☐ Purchased abroad
    - ☐ I do not know

Other drugs

List or describe what other medicines, herbal or dietary supplements were used.

30. Name of medicinal product
31. Reason for treatment
32. Treatment start date
33. Treatment end date
34. Additional information on other drugs

Additional questions

35. Any additional information
36. Have you notified anyone in the health care of the adverse reaction?
    - O Yes,
        - O Physician
        - O Dentist
        - O Nurse
        - O Other health care professional
    - O No
    - O I do not know

For further information contact:

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