EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 January 2014
EMA/56108/2014
Patients and Healthcare Professionals Department

Guidance on ADR reporting

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Reporting side effects

Guidance for Patients

Did you know you can now report side effects of medicines?

As a patient, you now have the right to report unwanted side effects of medicines directly to the authorities. You can also report a side effect on behalf of someone you are caring for, such as a child or relative.

Why report a side effect?

We are always learning more about medicines. Although they are tested extensively before they are authorised, not everything can be known about their side effects until they have been used by many people and for some time. By reporting side effects, you will be helping to find out more information, which will ultimately lead to safer medicines.

How to report a side effect?

If you think a medicine you have taken has caused a side effect, please check the package leaflet that comes with your medicine for information on the ways to report it. You can report side effects to authorities by:

- filling in an online form (link)
- reporting over the telephone (see your package leaflet)
- filling in a form from your doctor or local pharmacy.

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What information should I report?

When you are reporting a side effect, you will be required to answer certain questions. You should answer them as completely as you can. If possible, have the following important information to hand when making your report:

- information on the person who has had the side effect (such as age and sex)
- the description of the side effect;
- the name of the medicine suspected to have caused the side effect (brand name as well as active ingredient);
- the batch number of the medicine (found on the packaging);
- any other medicines being taken at around the same time (including herbal remedies or non-prescription medicines);
- any other health conditions that you or the person who experienced the side effect may have had at the time.

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Frequently asked questions

How do I know I have experienced a side effect?

A side effect (also called an adverse reaction) is an unwanted symptom or effect caused by a medicine. You cannot always be certain whether what you are experiencing is caused by the medicine, but by reporting suspected side effects, you help authorities in their investigations and this will help you and other patients be better informed.

What will happen to my report when I have sent it?

Once received, yours and other reports will be reviewed by medicines safety experts to see if there is new relevant information, what is known as a 'safety signal'. After evaluating the safety signal and all other relevant data, medicines authorities may issue new warnings or advice on how the medicine should be used.

Can I get help in reporting my side effect?

Yes. Your doctor or pharmacist can help you complete your report and you can also request that they send the report on your behalf. Patients' organisations in your country may also be able to help.

My medicine has a black triangle symbol in its package leaflet. What does this mean?

The inverted black triangle symbol '▼' serves as a reminder to patients and healthcare professionals to report any suspected side effects, either because the medicine is new or because there is a particular need to find out more about its long-term safety. The symbol does not mean that your medicine is unsafe.

Is my anonymity protected?

All personal information that could identify the person making a report or the person who has had a side effect is treated as strictly confidential. Your report is used solely for the scientific evaluation of your medicine.

Where can I find information on reports from other patients?

You can check the publicly available European database to find information on reports from other patients (www.adrreports.eu). You can also request information from your national medicines authority.