



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Question and answer document on the European database of adverse drug reaction reports website

### 1. About the website

#### What information can I find on the website?

You can view information on reports of suspected side effects (also known as suspected adverse drug reactions) for authorised medicines in the European Economic Area (EEA). This information is presented in a format called a web report. Currently, the information only relates to medicines authorised through the centralised procedure managed by the European Medicines Agency.

#### Where does the information on suspected side effects come from?

All information on suspected side effects on this website is derived from [EudraVigilance](#), a database designed for collecting reports on suspected side effects, which can be used for evaluating the benefits and risks of medicines during their development and monitoring their safety following their authorisation in the EEA. The data in EudraVigilance is submitted electronically by national medicines regulatory authorities and by the pharmaceutical companies that hold the marketing authorisation for the medicines.

#### Why is the European Medicines Agency publishing this information?

The website was launched to comply with the EudraVigilance Access Policy, which was developed to improve public health by supporting the safety-monitoring of medicines and to increase the European Medicines Agency's level of transparency. Transparency is a key guiding principle of the Agency, and is recognised as pivotal to building trust and confidence in the Agency's work. Efforts to increase transparency are important because, by releasing more information online, the Agency is better able to address the increasing demand for information from its stakeholders, including the general public.

### 2. About the web reports on the website

#### If a web report for a medicine is published on the website, does it mean that the medicine is dangerous and that I should stop taking it?



No. If a medicine is authorised for use in the EEA, it means that its benefits are considered to outweigh its risks, if used as authorised. The benefit-risk balance is determined after a careful assessment of the benefits and side effects of the medicine.

The information contained in a web report includes suspected side effects that may or may not be related to or caused by a medicine or active substance. Therefore, information in a web report should not be interpreted as meaning that the medicine or active substance causes a particular effect. The information cannot be used in isolation to decide upon the benefit-risk balance of a medicine.

If you have concerns about a medicine you are taking, you are advised to speak to a healthcare professional.

### **What type of information on suspected side effects is available in a web report?**

The information available is in line with the criteria defined in the EudraVigilance Access Policy; web reports provide aggregated information on suspected side effects, using data elements from the reports submitted to EudraVigilance.

### **When I look at a web report, I notice that the number of reported cases for a medicine or active substance can decrease over time. Why is that?**

The EudraVigilance system (from which data for the web reports are taken) is a 'living' database that is constantly updated and maintained to ensure high quality. The figure displayed online is a running total of the serious spontaneous cases of suspected side effects reported up to the end of the previous month. The figures are updated online on the 15th of the current month. The number of cases can decrease from one month to the next for one or more of the following reasons:

- a follow-up report of an existing individual case is received where the reported medicine, reported active substance or reported suspected side effect is modified by the reporter, based on new information;
- a report is submitted by more than one reporter (e.g. a pharmacist and a doctor); during quality review, these duplicate reports can be identified and are combined into a single report;
- a report can be removed at the sender's request, usually due to the report being erroneous.

## **3. About side effects**

### **What is a side effect?**

A side effect (also known as an adverse drug reaction) is defined in European legislation as "a response to a medicinal product which is noxious and unintended". This includes side effects arising from use of a medicine within the terms of the marketing authorisation (e.g. the authorised indications), as well as from use outside the terms of the marketing authorisation, including overdose, misuse, abuse and medication errors, and suspected adverse reactions associated with occupational exposure.

### **How can I find information on the known side effects associated with a medicine?**

A medicine's known side effects are listed in the summary of product characteristics (SmPC) and package leaflet that are produced for every medicine authorised in the EEA. The SmPC and package leaflet also give instructions on how the medicine should be used. The package leaflet is written in language that is easy to understand.

For the SmPC and package leaflet of a medicine that has been authorised for use in the EEA through

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the centralised procedure, you can search the website of the European Medicines Agency, which manages this procedure. For the SmPC of a nationally authorised medicine, you should go to the website of the national medicines regulatory authority in your country.

### **Why are side effects monitored?**

Before a medicine is marketed, safety and efficacy information is mainly limited to the experience gained in clinical trials, which may only detect the more common side effects. Some important side effects may be rare, delayed or not directly related to the pharmacological property of the medicine.

In addition, the controlled conditions under which patients receive medicines in clinical trials (direct medical supervision, no significant exposure to other medicines, absence of underlying diseases, etc.) do not necessarily reflect those under which the medicine will be used in the 'real' world.

Continuous monitoring of suspected side effects is essential for detecting and managing new or changing risks, as well as for managing risks that are already known.

### **How are suspected side effects monitored by the authorities in the European Economic Area (EEA)?**

The reporting of suspected side effects in a consistent way across the EEA is very important as it helps to monitor the benefits and risks of medicines and to detect emerging safety signals. A safety signal can be defined as new information related to side effects or any other medicine-related problem that requires further investigation. Within EudraVigilance, signals are detected by performing regular analyses of reports on suspected side effects.

Expert evaluation of safety signals is necessary, to determine the likelihood of the association between the suspected side effect and the medicine, and to determine whether any regulatory action is necessary. Typical information that must be taken into account includes the frequency, severity, plausibility and quality of the information contained in the reports, the dose of medicine taken by the patient, the time to appearance of the side effect, any underlying diseases, the simultaneous use of other medicines, and evidence of disappearance or reappearance of the side effect once the medicine was discontinued or reintroduced. When assessing a signal, consideration is also given to whether an error in the use of the medicine or a quality defect during the manufacture of the medicine may have occurred.

Side-effect reporting is just one of the elements taken into account by European authorities when assessing the safety of a medicine. Information can also be gathered from additional sources, such as:

- clinical and epidemiological studies;
- medical literature published worldwide;
- rates of morbidity (incidence of ill health in a population) and of mortality (incidence of death in a population).

Additional investigative studies, and sometimes consultations with other national medicines regulatory authorities, are often necessary to confirm that a suspected side effect is linked to a medicine. These investigations attempt to assess the likelihood that the medicine caused or contributed to the effect, to identify risk factors, and to estimate the frequency of occurrence.

## 4. Reporting suspected side effects

### Who reports suspected side effects?

Patients, consumers and healthcare professionals report suspected side effects to either the national medicines regulatory authority or the pharmaceutical company that holds the marketing authorisation for the medicine. These reports are then transmitted electronically to EudraVigilance.

Package leaflets remind patients to talk to their healthcare professional about any suspected side effect, while in some Member States, national reporting schemes already exist for patients. EU legislation requires that methods for direct reporting by patients and consumers will be supported in all countries of the EEA. More information on direct patient reporting in your country may be available on the website of your national authority.

### What should I do if I or someone I know experiences a side effect?

If you suspect that you are experiencing a side effect you should consult a healthcare professional. Side effects are usually reported by healthcare professionals, but increasingly, patients and consumers are able to report suspected side effects directly to national medicines regulatory authorities or marketing-authorisation holders through online patient reporting forms or by telephone. See the list of national medicines regulatory authorities in the EEA to contact the relevant one for your country and find out if direct patient reporting is available.

The European Medicines Agency cannot accept side-effect reports directly from patients or consumers. The Agency is also not in a position to provide individual medical advice or to confirm whether your symptoms are being caused by your medicine.

### I am a healthcare professional; how can I report a side effect experienced by my patient?

You should contact your national medicines regulatory authority for advice on how to report side effects. National authorities have put various methods in place to facilitate the reporting of suspected side effects, and healthcare professionals play a critical role in monitoring the safe use of medicines.

The European Medicines Agency cannot accept reports directly from healthcare professionals and does not submit reports to the EudraVigilance system on behalf of healthcare professionals.

### What is pharmacovigilance?

Pharmacovigilance has been defined by the World Health Organization as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. The name is derived from the words *pharmaco* (Greek for 'medicine') and *vigilantia* (Latin for 'vigilance, watchfulness').

### What is EudraVigilance?

EudraVigilance is a system designed for collecting reports of suspected side effects. These reports are used for evaluating the benefits and risks of medicines during their development and monitoring their safety following their authorisation in the European Economic Area (EEA). It has been in use since December 2001. The system is developed and maintained by the European Medicines Agency.

### What type of information is contained in reports of suspected side effects submitted to EudraVigilance?

The reports contain information about the patient, including relevant medical history, plus details about the side effect(s) suspected to be associated with the medicine(s), the treatment given and the final outcome(s) of the side effect for the patient.

## **What is the regulatory framework for reporting to EudraVigilance?**

The reporting obligations of the various stakeholders are defined in European legislation, in particular Regulation (EC) No 726/2004 as amended, Directive 2001/83/EC as amended and Directive 2001/20/EC. See the EudraVigilance website for further information on reporting obligations. Details on the processes for the conduct of pharmacovigilance in the European Economic Area can be found in Volume 9A of the Rules governing medicinal products in the EU.

## **What is the Medical Dictionary for Regulatory Activities (MedDRA)\*?**

MedDRA is a dictionary of medical terminology. It is used to classify clinical information in EudraVigilance and, subsequently, information on this website. MedDRA was developed to support the encoding of several types of clinical information collected during the clinical development and marketing of medicines. Besides side effects (including diseases, diagnoses, signs and symptoms), MedDRA supports the encoding of medical and social history, indications for use of the medicines, investigations and physical examination findings. MedDRA is the international standard terminology dictionary used for regulatory safety-reporting of pharmaceutical medicines. It was developed by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

\* MedDRA is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).

## **5. About regulatory action**

### **What information is needed for European authorities to initiate regulatory action in respect of a medicine or active substance?**

Regulatory action to protect or promote public health is taken in accordance with the regulatory framework and must be based on scientific analysis. This implies an evaluation of the safety signal and an appropriate benefit-risk review of the information available. Collaboration between stakeholders, including scientific experts, healthcare professionals, pharmaceutical industry, national regulatory authorities, patients and consumers, is commonly needed to provide all the information necessary for regulatory action. The type of action may vary, depending on the nature, the seriousness and the frequency of the side effect, as well as on the intended use of the medicine, the benefits obtained from its use versus the risks, and the availability of alternative therapies.

### **What regulatory action can be taken if a problem with a medicine or active substance has been confirmed?**

If a problem with a medicine or active substance has been confirmed through scientific assessment, the possible regulatory actions that can be taken include:

- conducting post-marketing studies to obtain further information on the safety profile of the medicine or active substance;
- carrying out a comprehensive reassessment of the benefit-risk profile of the medicine or active substance;
- changing the product information (for example to add contraindications, warnings, precautions or supplementary information on side effects);
- altering the labelling to clearly identify risks and instructions on the use of the medicine;

- disseminating information to healthcare professionals and consumers about the risks (through letters, advisories, publications or specialised internet sites);
- adding warnings to the patient information leaflet;
- issuing safety communications such as press releases;
- suspending the marketing authorisation;
- withdrawing the medicine from the market.

Implementing regulatory actions is the responsibility of both European and national authorities. For more information on this, see Chapter 3 of the Introduction of Volume 9A of the

For any questions on this Q&A document, write to [info@ema.europa.eu](mailto:info@ema.europa.eu).