

A background image showing the profiles of three women of different ethnicities (Black, White, and Asian) looking towards the right, set against a blurred outdoor background.

# VigiAccess™

**INSPIRE. ENGAGE. TRANSFORM.**

- Find information about suspected side effects
- Learn more about medicines and safety
- Get a global perspective on how drugs interact with people

# A vital role for all

**Monitoring the side effects** of medicines has long contributed to improved patient safety. We can all make a key contribution to this crucial activity by being more aware of how our body interacts with the medicines we take, by making sure we use only good quality medicines, and by talking to our doctors about any unwanted effects.

## **Pharmacovigilance – monitoring the medicines we take**

Medicines may cause unexpected side effects that can vary from individual to individual. Many of these effects, also called adverse drug reactions, are detected during drug development, but since only a restricted number of selected patients are treated during this phase, it is unlikely that rare adverse reactions will be observed. Then, as the drug becomes available on the market and more people take it, previously unknown effects are likely to emerge.

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems. Side effects are a common cause for patients to stop

**Pharmacovigilance is of paramount importance for ensuring the safe use of medicines.**

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following their doctor's instructions and complete their treatment, which could lead to further serious problems. In addition, low quality and falsified medicines can also cause harm, or not work at all, increasing our chances of experiencing an unwanted effect.

Reporting suspected adverse reactions thus offers the opportunity to identify and further investigate previously unknown or poorly described side effects. This is of paramount importance to help ensure the safe use of medicines, and is essential as long as a medicine remains on the market.

New initiatives are now available to help us all understand better the relation between medicines and our own well-being within a global perspective.

## **A global perspective in a personal relation**

VigiAccess is a user-friendly interface that allows everyone to search VigiBase®, the WHO global database of adverse drug reactions, and retrieve statistical data on the suspected adverse reactions of medicines



reported to the WHO Programme for International Drug Monitoring.

VigiAccess helps us understand how our bodies interact with medicines and enables us to learn more about possible side effects. The more we know about suspected adverse drug reactions and the more information we share, the more we can contribute to better treatment effects and well being.

The interface format displays easy-to-understand information and helps us see if our suspected side effect has previously

been reported as a supposed reaction to the medicine we are taking. Access to more information will give us knowledge for a better dialogue with our healthcare professional. VigiAccess respects patient confidentiality and data protection, which is why the information is only available at continental and not country level.

VigiBase is an important reference source with over 10 million reports going back to 1968. It contains reports of suspected relationships between a drug and an adverse reaction, but it is crucial

to understand that no causal relation has been confirmed. Also, not all side effects are reported since many countries face enormous public health challenges with little awareness of adverse drug reactions among the population. The mechanisms to support a more active reporting role may also be lacking.

Since 1978, UMC has been the maintenance organisation for Vigibase, providing scientific leadership and operational support to the WHO Programme for International Drug Monitoring and expanding the global network to more than 90% of the WHO member countries.

UMC's efforts have helped build global pharmacovigilance capacity and, by providing access to resources and tailor-made support, encouraged local and regional initiatives. Vigibase is the latest tool developed by UMC to promote pharmacovigilance and improve patient safety. Most importantly, it's available to the general public.

### **A more active role for patients**

If you suspect that you have experienced an adverse reaction, talk to your doctor about the symptoms and discuss together the measures that you should take. Your doctor has the responsibility to report serious unknown adverse reactions to your country's national pharmacovigilance centre as part of the WHO Programme for International Drug Monitoring. In many countries, patients and consumers are encouraged to report adverse drug reactions themselves if they wish. Visit the website of the National Regulatory Authority for Medicines or the National Centre for Pharmacovigilance for more information, or ask your healthcare provider.

**Always discuss unexpected side effects with your doctor**

**Learn more about the medicines you take and their possible side effects**



# Frequently asked questions

## 1. What should I do if I suspect I am having an unexpected side effect?

Always contact your doctor if you suspect that you are experiencing an adverse drug reaction. Your doctor will provide the advice you need and report the event to your country's national pharmacovigilance centre.

## 2. Should I stop taking a medicine if I suspect I am having an unexpected side effect?

No. Do not discontinue your medication or change the dose without seeking the advice of your healthcare provider. VigiBase is only a reference source and no causal relation has been confirmed. Individual decisions must always be taken between patient and doctor. Good communication is the key to balancing the benefit and risk of a medicine.

## 3. Are vaccines also medicines?

Vaccines are also medicines and, since they can also cause unwanted effects, are monitored like medicines.

## 4. What happens once an adverse reaction has been reported?

The national centre for pharmacovigilance evaluates the report to identify potential risks. Together with the relevant authority, it can then take measures to minimize this risk if deemed appropriate. Countries participating in the WHO Programme for International Drug Monitoring then forward

the reports to VigiBase. Note that all reports sent to VigiBase are anonymous; the patients, healthcare professionals or institutions involved cannot be identified. UMC regularly screens the uploaded data to better identify, characterise and understand the potential risks of the medicine. It then shares the findings with national centres, the WHO and the public via various channels. More information can be found on the UMC website: [www.who-umc.org](http://www.who-umc.org)

## 5. Why can I retrieve data only at continental and not country level?

This ensures that patients, reporters or treating institutions cannot be identified; in rare cases a small number of reports in a specific country might lead to a breach of privacy. If you need more information at country level, your national pharmacovigilance centre may be able to help you, but always in compliance with local data protection laws.

## 6. What can we learn from the information in a reporting system?

A spontaneous reporting system provides very important information on potential risks and helps identify groups of patients or situations in which particular attention or special monitoring might be needed. Since it covers all populations treated as long as a medicine is available on the market, the information gathered from a spontaneous reporting system is unique. It is also very cost effective!

## 7. What is the safety profile of a medicine?

The safety profile provides information about the possible risks associated with a medicinal drug. Patients and healthcare professionals need to make a benefit / risk assessment to make an informed decision that best responds to patient needs and specific conditions.

## 8. Can I compare the safety profile of different medicines using data from VigiBase?

No, this is not possible. Note also that this reporting (so-called spontaneous reporting) refers only to suspected causal relationships between a drug and an adverse event, without this relationship being proven. It is thus not possible to compare different drugs based solely on reported information, or to conclude that one drug is safer / less safe than another.

## 9. What does a national centre for pharmacovigilance do?

National centres work either within the local regulatory authority or Ministry of

Health or on behalf of them. They collect and evaluate spontaneous reports on adverse reactions to medicines, advise relevant authorities, and act as drug information centres for healthcare professionals and the public. Their activities vary greatly depending on national needs and resources.

## 10. What is a regulatory authority?

In most countries, this is the authority in charge of ensuring that only effective medicines of good quality and with a positive benefit / risk balance (i.e. the benefits outweigh the risks) are available on the market. Well known regulatory authorities are the US Food and Drug Administration (US FDA) and the European Medicines Agency (EMA). In some countries the regulatory authority is part of the Ministry of Health, in others it is a separate entity.

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### The World Health Organization

The World Health Organization (WHO) is the directing and coordinating authority for health within the United Nations system. It provides leadership on global health matters, shapes the health research agenda, provides technical support to countries,

and monitors and assesses health trends. It regards health as a shared responsibility, involving equitable access to essential care, and is committed to addressing persisting problems as well as new threats to public health emerging during the 21st century. For more information visit [www.who.int](http://www.who.int)

### IN BRIEF

VigiAccess simplifies retrieving and sharing key information from the VigiBase adverse reactions database and offers a global overview of unexpected side effects.

A photograph of a woman with long, dark, wavy hair smiling warmly at the camera. She is holding a young child with short, dark hair who is also smiling. The woman is wearing a blue and white checkered top and a dark red strap across her shoulder. The child is wearing a light-colored, vertically striped shirt. They are outdoors in a grassy area with a blurred background of trees and sunlight.

**VISIT THE  
VIGIACCESS  
WEB PAGE**

[WWW.VIGIACCESS.ORG](http://WWW.VIGIACCESS.ORG)

VigiAccess contributes to our understanding of medicines and how we interact with them; it encourages us to report unexpected side effects and boosts our contribution to a global safety culture. For more information, please visit [www.who-umc.org](http://www.who-umc.org)

## Inspire. Engage. Transform.

Uppsala Monitoring Centre advances the science of pharmacovigilance and **inspires** patient safety initiatives all over the world. As an independent, non-profit foundation, we **engage** stakeholders who share our vision and collaborate to build a global patient safety culture. As a leader in the research and development of new scientific methods, we explore the benefits and risks of medicines to help minimize harm to patients, and offer products and services used by health authorities and life-science companies worldwide. Our unique expertise makes us an organisation with the capacity to **transform** patient safety from an ambition into a reality. For almost 40 years, we have provided scientific leadership and operational support to the WHO Programme for International Drug Monitoring, expanding the global pharmacovigilance network to reach more than 95% of the world's population.



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