Adverse Event Reporting

What is pharmacovigilance?

Pharmacovigilance is the science and process associated with the detection, evaluation, understanding and prevention of adverse reactions or other problems relating to medicines/medicinal products.

Prior to the approval of a medicine for use, evidence that it is safe and effective is limited to the results gathered from clinical trials in which patients are carefully selected and carefully monitored under highly controlled conditions. This means that when it is first registered, the medicinal product has been tested on a relatively small number of selected patients for a limited period.

After approval, the medicine can be used by a large number of patients for a long period of time and in conjunction with other medicinal products. Under these circumstances some patients may develop certain side effects/adverse reactions.

This is why it is essential to monitor the safety of all medicines for the duration of their use in healthcare.

If you suspect an adverse reaction or want more information about the safety of Novartis medicinal products, please consult your doctor or pharmacist.

Any suspected adverse reactions to our medicinal products can be reported to us by email or by calling our free helpline.

- **Generic email:** safety.cz@novartis.com
- **Telephone: +420 225 77 51 11**

Patients and healthcare professionals can also report adverse events by using the form on the State Institute for Drug Control website at www.sukl.cz

What information do we need?

An adverse reaction is an unfavourable and unintended response to an administered medicinal product.

What other information are we interested in with regard to our products?

Exposure during pregnancy or when breastfeeding, lack of efficacy, drug and food interactions, errors in medication, exposure to a medicinal product at work, progression and worsening of the illness, failure to follow the prescribed treatment regimen, overdose, intentional misuse, substance abuse, drug dependence, transmission of infectious agents, abnormal results of laboratory and diagnostic tests, allergic reactions, unexpected beneficial effects, use for other than specified indications.

Personal data processing policy for the purposes of patient safety, medical information and quality

1. https://prod1.novartis.cz/cz-en/cz-en/en/patients-and-caregivers/adverse-event-reporting
2. mailto:safety.cz@novartis.com
3. http://www.sukl.cz
4. https://prod1.novartis.cz/cz-en/cz-en/en/privacy-policy