

## **To the attention of interested persons**

The National Agency for Medicines and Medical Devices (NAMMD) hereby informs on availability of a form for reporting of adverse reactions to medicinal products, including vaccines, by patients, patient relatives or caregivers. The form for reporting adverse reactions available to patients, by means of which patients, their relatives or caregivers can notify adverse reactions following administration of medicinal products, vaccines included. The suspected adverse reaction reporting form is posted on the NAMMD website, together with a number of related clarifications and pieces of information.

**According to Marius Savu, MD, President of the National Agency for Medicines and Medical Devices, “The National Agency for Medicines and Medical Devices (NAMMD) encourages patients, caregivers, healthcare professionals (physicians, pharmacists, assistants) to report suspected adverse reactions to medicinal products, vaccines included. Additional information on the safety of medicinal products, including vaccines, can only be determined from reports. In this manner, every member of the public can contribute to safeguard their own and other people’s health. If, for instance, there are several reports of adverse reactions following administration of the same medicinal product, additional checks on safety are to be performed at both national and European level”.**

If you experience any adverse reaction to medicinal products, vaccines included, talk to your doctor or pharmacist. This includes any possible adverse reaction, listed in the leaflet or not. Should there, for instance, several adverse reaction reports occur, concerning administration of the same medicinal product, your doctor decides on the need for medical treatment or discontinuation/change of treatment.

### **What is an adverse reaction?**

An adverse reaction can be defined as „a harmful and unwanted response to a medicinal product”. Unwanted effects occurring after overdose, misuse, abuse of a medicinal product and medication errors or unwanted effects arising from professional exposure are also considered adverse reactions.

2050 reports of serious and non-serious adverse reactions were recorded in 2014, in Romania. As opposed to other member states of the European Union, this number is still low. For instance, in countries such as France and Great Britain, the number of reports is about 40,000 adverse reactions per year.

Therefore, the NAMMD encourages patients and their caregivers to report adverse reactions, by means of the adverse reaction reporting form, available on the Agency’s website at: [http://www.anm.ro/anmdm/med\\_reactie\\_adversa.html](http://www.anm.ro/anmdm/med_reactie_adversa.html)