**Learning unit: Pharmacovigilance**

**Impact of the learning unit:**

The pharmacotherapy is associated with a risk of adverse effects. The aim of the learning unit is to familiarize the student with the generally valid and legally binding procedures of pharmacovigilance, i.e. monitoring and reporting of adverse drug reactions.

**Relevant terms**

phamacovigilance

adverse reaction

adverse effect

serious adverse effect

unexpected adverse effect

suspicion of severe and unexpected adverse effect

EudraVigilance

regulatory authority

clinical trial phase IV

**Learning outcomes**

The student distinguishes between serious and non-serious, between expected and unexpected adverse effect of drugs.

The student is able to describe the characteristics of a phase IV clinical trial of medicinal products. The student enumerates subjects involved in the system of collecting and evaluating information about the adverse effects of drugs and can describe the role of the physician and his responsibilities in this system.

**Study literature**

<http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000679.jsp&mid=WC0b01ac05800250b5>

<http://www.sukl.eu/medicines/pharmacovigilance>

CIOMS form <https://cioms.ch/wp-content/uploads/2018/09/CIOMS-to-E2B-1.pdf>

FDA form <https://www.accessdata.fda.gov/scripts/MedWatchLearn/adverse_effects/default.htm>

**Exam questions**

*General pharmacology*: 23. Pharmacovigilance, drug safety, advertisement and marketing on the field of therapeutics, ethical issues