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