SIDE EFFECTS OF OFF LABEL DRUGS

Lukianchuk J. O.
Scientific supervisor: prof. Drogovoz S. M.
National University of Pharmacy, Kharkiv, Ukraine
Julia.olegovna95@gmail.com

Introduction. In most countries in the world where drug turnover (LS) is regulated at the legislative level, medications should be licensed by the regulatory authorities (FDA, HEC) for their use so that doctors and patients can use them. Before a drug must appear in the pharmaceutical market, a favorable balance between its use and harmful effects must be proven. The purpose of drug licensing is to ensure their use after the registration of high-quality, safe and effective drugs, and also after it has been proven that the benefits of their use prevail over the risk.

Aim. In most cases, the use of medication on indications not included in the instruction is prohibited. However, in real medical practice, the appointment of off label drugs is very common in all areas of medicine, and for some drugs it is a common practice, especially in pediatrics, psychiatry and oncology.

Materials and methods. Analysis of the normative basis for the use of off-label in Ukraine and in the world.

Results and discussion. According to the World Health Organization (WHO), half of all medicines have been prescribed according to indications that were not in the instructions and such use of the drug was called off label. As long as off label medications are effective, safe, well tolerated and relatively inexpensive, their use is not anxiety. However, despite of the benefits of using off label drugs, but the lack of regulation by health authorities, they can create certain risks in this area. Therefore, one of the potential concerns for physicians is that off label medicines do not always have convincing scientific support, which may not always be a known risk from the use of the drug for the patient and the doctor. Sometimes off label use of the medication carries more heightened risks for the patient and the doctor than his counterpart, a registered remedy that has an approved instruction. According to the results of the analytical analysis, the serious consequences of the use of off label medicines develop in 68.2% of the cases, including fatal outcomes - 9.8% of cases (10.4% of them are fatal outcomes in children from 0 to 9 years) The most frequent errors leading to fatal outcomes is the off label of the drug in inadequate doses (40.9%), irrational drug selection (16%) and incorrect route of administration (9.5%). In pharmacology, axioms are adhered to, if the drug is used in different directions of pharmacotherapy, then a higher risk of its toxicity should be expected. The safety of off label drugs is largely due to the risk of their adverse reactions and the particularly high risk of side effects of drugs is associated with the use of off label in children. Many problems in pediatrics arise because of the absence or limitation of evidence of side effects and contraindications to off label drugs, especially for rare diseases in children.

Conclusions. Consequently, in the health system, misuse of off label drugs is a serious concern about their safety, especially when the drug is widely used, regardless of the fact that regulators did not determine the risk-benefit ratio for it. Decisions on the prescription of any medications should always be weighed against the potential benefit and the possibility of harm. It must be remembered that prescribing a medicine is one of the most risky actions that a physician performs with a patient.

PATHOLOGICAL EFFECTS OF SUSTANON ON THE LIVER

Maksimovich A. S., Nedovesova Y. R.
Scientific supervisor: prof. Kononenko N. M.
National University of Pharmacy, Kharkiv, Ukraine
patology@nuph.edu.ua

Introduction. The phenomenon of abusing Anabolic androgenic steroids (AAS) by many youth and athletes is aserious health phenomenon which increase rapidly in recent years. Sustanon (Androgenicum prolongatum) is one of these AAS and has many useful pharmacological effects. It is used to treat cases of osteoporosis, male hypogonadism and infertility. Sustanon is characterized by a unique